NICE National Institute for Health and Care Excellence

NICE HealthTech programme manual consultation

23 October 2025

This document provides themed response to the consultation comments received on proposed updates to the NICE HealthTech programme manual (PMG48), and proposed amendments to the NICE interventional procedures manual (PMG28) and NICE health technology evaluations: the manual (PMG36). It also responds to comments and input received as part of the after action reviews (AARs) that were held following the completion of the initial late stage assessment (LSA) topics.

1. A public consultation was held between 1st August and 4th September 2025. Stakeholders were given the opportunity to provide detailed comments and responses on the consultation documents.

2. We received 468 responses from 28 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	13	51%
Trade bodies/associations	3	18%
External Assessment Groups (EAGs) and academic institutions	5	22%
Voluntary and community sector organisations	5	5%
NHSE, NHS trusts, NHS network groups	2	4%

3. Following the completion of the initial late stage assessment (LSA) topics, after action reviews (AARs) were held. Feedback was obtained through surveys sent out after publication of guidance to all registered stakeholders for

the topic. In addition, an external AAR session was held for all topics, as an opportunity to discuss elements of the LSA process and methods and provide NICE with feedback. Stakeholders invited to these sessions included the Department of Health and Social Care, the NHS Business Services Authority, NHS Supply Chain, companies with products assessed in the relevant LSA topics, the British Healthcare Trades Association (BHTA), the Association of British Healthcare Industries (ABHI) and patient organisation representatives. Feedback received as part of the AARs has been considered alongside the consultation comments received in the below responses and updates to the manual text. In addition, a specific section (section 18) identifies key themes from the AARs and what we are doing in response.

Findings from the consultation and AARs, implications, and next steps

Section 1 - Decisions about topic routing and what lifecycle approach to take for guidance

Summary of comments received

4. Respondents commented that the principles outlined for decisions about what lifecycle stage guidance will be developed (for early, routine or existing use guidance) may be considered subjective. They requested greater clarification and guidance be provided about the factors that are used to decide what evaluation pathway a technology would be assessing using. In particular, the distinction between ‘routine’ and ‘existing’ use was highlighted as potentially problematic. Respondents also requested that the decision making approach be subject to stakeholder consultation prior to finalisation of the guidance.

5. Respondents also asked for clarification on the decision-making process for Interventional Procedures guidance, and how a technology may be referred from Interventional Procedures guidance to HealthTech guidance.

Our response and any changes to the NICE HealthTech programme document

6. Greater detail has been added to the manual (section 2.1.28) on the principles that identify which lifecycle approach to take for guidance. The updated table 2 from the HealthTech manual has been copied below (added or amended text is underlined). Definitions used to define innovation levels are from an existing framework (the Department of Health & Social Care's Medical technology innovation classification framework), which was developed with engagement from multiple stakeholders (stakeholder organisations are listed in appendix C in the cited webpage).

Table 2 General principles used to determine what lifecycle approach to take for producing guidance (from PMG48)

Lifecycle approach	General principles for selecting which lifecycle approach to take
Early use	• Limited or no current use in NHS • Limited evidence available for all technologies • Technologies have the potential to address a high unmet need in the NHS • Usually recent, ongoing or upcoming appropriate regulatory approval for use in the UK
Routine use	• Greater level of evidence available that means some technologies may be suitable for routine widespread use in the NHS • Any technologies that have been previously assessed in early use guidance and have gone through the evidence generation period • The assessed group of technologies (interventions) are not considered established practice in the NHS, so a comparator separate to the intervention(s) can be defined. See section 2.1.5 for greater detail on how established practice is determined • Technologies that are potential transformative or disruptive innovations, as defined in the Department of Health & Social Care's Medical technology innovation classification framework, are likely to be assessed in routine use guidance
Existing use	• The assessed group of technologies (interventions) comprise of similar technologies at least some of which would be considered established practice in the NHS.

	See section 2.1.5 for greater detail on how established practice is determined • Technologies that are potential incremental innovations, continuous improvements or copycat devices (as defined in the Department of Health & Social Care's Medical technology innovation classification framework) are likely to be assessed in existing use guidance • There is likely to be variation in price between alternative technologies in the assessed group of technologies

7. The choice about which guidance lifecycle approach to take will be made by NICE. But this will consider input from stakeholders, including companies, during the scoping process, for example at a scoping workshop. In making the decision NICE considers what type of guidance will be most useful and usable to the health and care system and how NICE can maximise value to the health and care system by producing guidance. Further text has been added to section 2.1.28 of the manual to include this further detail.

8. NICE-wide topic prioritisation: the manual sets out the process for how new guidance topics and updates to existing NICE guidance are identified, prioritised and routed at NICE. This includes eligibility criteria for new interventional procedures (see section 7.1.2). Where there is uncertainty about the decision about what type of guidance NICE will produce (that is, routing) that requires a decision from the NICE prioritisation board, a topic briefing can be developed for use with the prioritisation framework (described in section 9 of this manual).

Section 2 - Regulatory approval of HealthTech and consideration in guidance

Summary of comments received

9. Respondents questioned why technologies not yet available in England or without appropriate regulatory approval may be included within a scope, and highlighted concern that NICE may issue guidance favouring technology that is not approved over others that are.

10. Respondents also questioned proposed manual text that comparators may include technologies that do not have regulatory approval for the population defined in the scope if they are considered established clinical practice in the NHS. They stated that they did not believe that comparison of regulated and unregulated products is appropriate. Respondents asked how what constitutes established clinical practice would be determined to justify the inclusion of comparators without appropriate regulatory approval.

Our response and any changes to the NICE HealthTech programme document

11. While technology without appropriate regulatory approval can be included in the scope and considered in the assessment, a recommendation for use will not typically be issued for such technologies until they have this approval (which may occur during the assessment phase). In situations where NICE does produce a recommendation for use of a technology that does not have appropriate regulatory approval, the recommendation will be accompanied with a statement that the technology can only be used once it has appropriate regulatory approval.

12. The option to include technologies that do not have regulatory approval as a comparator is existing practice for HealthTech guidance programmes, as has previously been set out in NICE health technology evaluations: the manual (PMG36, see section 2.2.13) so this does not constitute a change in approach. It is a pragmatic way to ensure that guidance is based on a realistic representation of what current care in the NHS is. To best understand this, the NICE team speak to healthcare professionals, look for relevant guidelines (from NICE and other organisations) and take advice from stakeholders during the scoping period, for example at scoping workshops.

Section 3 – Further guidance and support

Summary of comments received

13. Respondents requested that NICE develop further guidance on:

- Use of real world evidence for committees to ensure consistency

- How to use linked evidence for diagnostic technologies
- How capacity related benefits should be assessed, quantified and incorporated into evaluations
- Evidentiary requirements for NICE guidance, including an evidence framework for technologies assessed for existing use guidance.

Our response and any changes to the NICE HealthTech programme document

14. NICE will look to provide further support for stakeholders and companies developing HealthTech. The provided suggestions are a useful guide to what further support would be beneficial.

15. A modular update is a review of the methods and/or processes that inform NICE guidance, that may result in an update to our manuals. Stakeholders can make suggestions to identify candidate topics for modular updates. This ensures that the manuals continue to meet our users' needs. The process for suggesting a modular update topic, and further details, can be found on the Modular updates page of the NICE website.

Section 4 – Severity modifier

Summary of comments received

16. Respondents stated that a severity modifier should also be applied to HealthTech guidance, as for medicines, to ensure fairness and parity across NICE's processes.

17. The lack of a severity modifier was highlighted as of particular concern for the rare disease community. Respondents commented that many device-based interventions also address severe or life-limiting conditions. They also stated that this creates an inequality in approach in terms of NICE's approach to HealthTech, contradicting the intention of the 10 year health plan to create parity of esteem between different health technologies.

Our response and any changes to the NICE HealthTech programme document

18. Section 2.4.5 of the HealthTech manual has been amended to state that initially the severity modifier will not be applied to HealthTech guidance. Here the severity of the condition should be captured within the QALY benefits and then deliberatively within decision making. We are currently exploring approaches on how the severity modifier could be applied for HealthTech guidance.

19. This approach aligns with NICE guidelines, as described in section 7.8 of Developing NICE guidelines: the manual:

“Initially, the severity modifiers introduced by the Centre for Health Technology Evaluation (CHTE) for technology appraisal guidance will not be applied to NICE guideline health economic analyses. For NICE guidelines, the severity of the condition should be captured within the QALY benefits and then deliberatively within decision making. However, to enable consistent decision making across NICE guidelines and technology appraisals and to foster better integration of NICE recommendations across these programmes, we are currently exploring approaches on how the severity modifier could be applied within NICE guidelines. We would consult with stakeholders ahead of any implementation.”

20. NICE Listens is our programme of deliberative public engagement. It is used to give us an understanding of public opinion on moral, ethical and social value issues. The NICE Listens web page includes details of a current project about valuing health gains in severe disease. The aim of this public dialogue is to investigate how the public thinks NICE should account for disease severity in its health technology evaluations. We’re also working on a stated preference study that will generate quantitative data from a large, representative sample. The research is being designed in a way that is technology-agnostic, so the findings could be applied to HealthTech and other non-drug interventions.

Section 5 – Assessment of groups or classes of technologies

Summary of comments received

21. Respondents commented that while grouping technologies can support consistent decision making, issuing recommendations at a class level risks disadvantaging innovative devices by treating them as interchangeable with less effective alternatives. They highlighted concerns about technology with no evidence gaining benefit from technologies with evidence.

22. Respondents questioned how meaningful differences between technologies will be recognised within class-level recommendations to ensure that patients and clinicians retain access to the most effective options. They requested further detail on what would be considered sufficient strength evidence to recommend specifying a technology from within a group in guidance or recommendations.

23. Respondents requested greater clarity on criteria and thresholds for technologies to be grouped or treated the same.

24. Stakeholders commented that group analysis is problematic and should either be removed or only used in rare circumstances.

25. Respondents commented that experience of the late stage assessments has demonstrated that comparing products that have shared features or functions when the selection of product is based on a personalised need will always lead to the same conclusion: that the patient need should be the leading consideration for product selection.

Our response and any changes to the NICE HealthTech programme document

26. Section 2.1.7 in the HealthTech manual has been amended to clarify that assessing technologies as a group or class will be considered when what the technologies do or how they function are very similar or the same. Assessing technologies as a class or group was permitted under previous manual text (see, for example, NICE health technology evaluations: the manual section

4.4.18) so assessing technologies in this way does not constitute a change from previous methods.

27. Text in the manual on making recommendations for interventions that are specified as a group or class of health technologies in scope (section 2.4.15) has been simplified to state that when technologies are defined as a group or class of health technologies in the scope, recommendations will be issued for the whole group or class. Aligned with the approach taken for Interventional Procedures guidance, further text has been added to section 2.4.15 to state that if named technologies (within the group or class of technologies) are specified in identified studies, this may be included in the assessment report and within the guidance document, but recommendations will not be issued for individual technologies.

28. If technologies are to be assessed as a group or class, this will be specified in the final scope. Decisions about how to define interventions will be done during scoping, with opportunities for stakeholders to input during this process, for example at a scoping workshop.

Section 6 – Evidence

Summary of comments received

29. Respondents commented that evidence developed by industry, particularly for late stage assessments, has been discounted and deemed biased. However, a message given to industry is that it had not developed sufficient evidence. Respondents asked that it is made clear that it is the quality of the evidence rather than who generates the evidence that takes precedence.

30. Respondents asked for proportionate evidence requirements. This should reflect the nature of the technology and viable and feasible expectations of what evidence can be expected. Further comments were made in relation to challenges for producing evidence for rarer conditions (see section 8 for discussion of comments related to rare diseases).

31. Respondents highlighted that the cost and difficulties of generating data, particularly on different iterations of technology that may be needed to justify a relatively small price difference between technologies, should be considered in evaluations. In particular, the challenges this poses for small and medium-sized enterprises.

32. Respondents stated that it was important to consider real world evidence and highlighted issues with requiring RCT evidence, particularly for diagnostic technologies. A requirement for RCTs could limit what technologies can be made available to patients.

33. Respondents stated that scrutiny of product technical files should be done as part of assessments, and that any post marketing surveillance information from companies could, or should, be reviewed.

34. Respondents also asked for greater detail on predecessor technology considerations, and how these would be dealt with.

35. Respondents requested clarification on how distributional cost-effectiveness analysis (DCEA) will be used in HealthTech guidance.

Our response and any changes to the NICE HealthTech programme document

36. Section 2.4.7 in the proposed manual text stated that the committee should be proportionate in its considerations and consider factors related to the technology and condition, and how feasible or realistic it is to generate further evidence to reduce uncertainty about cost effectiveness.

37. Section 2.2.3 in the proposed manual text stated that all types of evidence can be considered for evaluations, not only RCTs. This can include any information provided by companies in response to requests for information. Section 4.3.3 on existing use guidance development states that post-market surveillance data may be used, if appropriate, when topics have little or no evidence, or to complement published clinical evidence.

38. External assessment groups (who produce the reports supporting committee considerations) are independent groups who review evidence and give their opinions about potential sources of bias (such as funding sources for studies). But it is ultimately the committee, not the assessment group, whose opinion on the evidence that determines the extent that it is considered and used in decision making.

39. Section 2.2.8 describes the use of evidence produced using predecessor versions of an assessed technology. This includes considerations for use of such evidence.

40. As described in NICE health technology evaluations: the manual (PMG36) at the time of the consultation (that is, August to September 2025), DCEA can be included in a company submission for technology appraisal guidance (if there is clear evidence of a significant burden of health inequalities in the eligible population). This manual also stated (in section 4.12.4) that DCEAs will not be done in economic evaluations produced by EAGs on behalf of NICE for HealthTech guidance and multiple technology appraisals. For these types of evaluations, DCEA evidence can be provided by companies as part of the information requested on the evidence base and their technology. As part of the work of this consultation in moving detail on HealthTech guidance from PMG36 to a separate manual - HealthTech evaluations to the NICE HealthTech programme manual (PMG48) – this approach has been retained. Section 2.3.5 in PMG48 has been updated to better align with the wording used in PMG36 (section 4.12.4, as discussed above). As described in this consultation, section 4.12.4 in PMG36 will also be updated to remove reference to HealthTech guidance (as this will be covered in the PMG48 manual). As described in section 2.4.4 of the HealthTech manual, aspects of assessed technologies that relate to health inequalities will be considered in decision making. NICE looks to identify and potential issues relating to health inequalities, including whether a technology could address inequality or unfairness in the distribution of health across society during scoping (see section 2.1.29 of the HealthTech manual). Input from stakeholders during the scoping process will inform this, as will any information provided in responses

to requests for information by companies or by other stakeholders (see sections 1.3.4 and 1.3.9 in NICE HealthTech programme manual).

Section 7 – Prioritising outcomes

Summary of comments received

41. Respondents asked how large the number of potentially relevant outcomes would need to be for the scope to prioritise or only include key outcomes that are most relevant to addressing the decision problem. They also questioned what input would be sought to inform this activity and raised concern that without a clear methodology selection of outcomes could be impacted by bias.

42. Respondents commented that if prioritisation of outcomes is necessary, it must ensure the collection of a wide range of patients' and carers' views to capture all outcomes relevant to the assessment. Also, that prioritisation of outcomes may be deleterious when assessing products such as intermittent catheters, given the personal aspect of continence care.

Our response and any changes to the NICE HealthTech programme document

43. The section of the manual that describes prioritisation of outcomes during scoping (section 2.1.26) has been updated to note that guidance on prioritising outcomes is provided by the GRADE working group. This is based on the approach for developing review questions set out in Developing NICE guidelines: the manual (see section 4.3) so provides consistency with approaches taken more widely across NICE. This section has also been amended to state that the scope may prioritise key outcomes that are most relevant to the decision problem, rather than only include such outcomes.

44. This section of the manual also highlights that this activity will be done during the scoping stage with input sought from stakeholders and experts, particularly people with lived experience of the relevant condition.

Section 8 – Rare diseases

Summary of comments received

45. Respondents stated that the update to the HealthTech Manual does not take into consideration the needs of the rare disease community, who have been identified as an underserved community, and therefore this is a health equity issue.

46. Respondents stated that there was a lack of flexibility for rare conditions in the proposed update, for example related to the cost-effectiveness threshold, and that it would be almost impossible to reach the standard cost effectiveness threshold. They stated that it is often not possible to meet the economies of scale required to produce a clinically validated product at the current standard cost-effectiveness threshold for HealthTech for rare diseases due to the relatively small groups of people that would benefit. Therefore, high incremental cost-effectiveness ratio (ICER) values are unavoidable due to fixed research and development costs spread across small patient numbers.

47. Respondents stated that there is greater flexibility given to medicines for rare disease, and proposed a similar pathway for HealthTech as for the Highly Specialised Technology (HST) pathway for medicines.

48. Respondents also commented that it is not always possible to carry out high quality clinical trials for HealthTech for rare disease, and such technologies should not be penalised if these types of studies simply are not feasible

Our response and any changes to the NICE HealthTech programme document

49. Decisions about what type of NICE guidance will be developed for new topics are made according to NICE-wide topic prioritisation: the manual. As described in section 7.1.4, for topics that involve the use of new health technologies (such as a medical device, diagnostic or digital technology), the prioritisation board may route a topic to several possible NICE guidance outputs, including highly specialised technologies guidance, if the technology

meets all the highly specialised technologies criteria (see routing criteria for highly specialised technologies).

50. The manual text does not state a maximum acceptable ICER but provides considerations for recommending a technology with an ICER over £20,000 per quality adjusted life year (QALY). These include considering if its decisions have a bearing on broader social considerations and the extent that these are covered by principles on social value judgements in our principles on the NICE website (which includes an aim to reduce health inequalities; principle 9).

51. Section 2.4.7 in the proposed manual text states that the committee should be proportionate in its considerations and consider factors related to the condition, and how feasible or realistic it is to generate further evidence to reduce uncertainty about cost effectiveness. Text has been added to this section to further clarify that, related to considerations about the relevant condition and evidence generation, this includes if the condition is rare.

Section 9 – Perspective for guidance development

Summary of comments received

52. Respondents stated that capturing the full benefits of the NHS 10-Year Plan's goals, shifting from sickness to prevention, hospital to community, and analogue to digital, requires an economic evaluation approach that extends beyond the current perspective to include wider societal impacts. This was stated to be essential to quantify benefits such as productivity gains from earlier diagnosis and reduced travel costs for patients and carers from community-based care. Respondents urged NICE to provide an update that offers clear guidance on the circumstances under which societal impacts can be included in evaluations, along with methods for measuring these benefits, to ensure that technologies are appropriately valued and to align with broader government objectives.

53. Respondents further stated that impacts such as service capacity, pathway efficiency, and system sustainability are critical to the NHS, and should be explicitly considered alongside QALY-based estimates.

Our response and any changes to the NICE HealthTech programme document

54. In December 2022, the NICE board reviewed an options appraisal for adopting a wider perspective in NICE assessments. The board concluded that NICE should retain its existing approach to perspective (using a health sector perspective in the reference case) while making use of flexibilities to consider wider effects in exceptional circumstances. NICE's position on perspective is continually under review as the methods and evidence base evolve.

55. The proposed manual text noted the importance of considering outcomes related to resource use and system efficiency in scopes for assessment (section 2.1.21), considering impacts on system efficiencies and capacity in economic evaluations (sections 2.3.16 to 2.3.18) and how any impacts that are not captured, or not fully captured, in cost-effectiveness estimates can be considered in decision making (sections 2.4.3 and 2.4.4).

Section 10 – General comments on existing use (late stage assessment) guidance

Summary of comments received

56. Respondents stated that assessment of existing use technologies appeared to place primary emphasis on cost containment and reducing cost. They stated that guidance overlooked the needs of patients and the role of clinicians in selecting products suitable for the clinical situation and patient needs. However, some respondents stated that, while text in the manual indicated that procurement and commissioning are key stakeholders for recommendations, many of the late stage assessment guidance topics published so far have been much more specific on how decision-making should be done at the healthcare professional and patient level.

57. Respondents also commented that a focus on product cost risks innovation not being sufficiently rewarded. If companies struggle to introduce innovative products, they might decide to exit the UK market or not introduce innovative products in the future. This will have a negative effect on patients, the wider healthcare system and the UK economy.

58. Respondents stated that the Department of Health and Social Care's National Standard Evaluation Methodology for Value Based Procurement approach is meant to ensure that all domains are considered and weighted accordingly to avoid price being considered in isolation. They recommended that this methodology is included in the methods and processes.

59. Respondents stated that further evaluations should be deferred until the publication of a finalised and comprehensive methods manual that ensures consistency and transparency. Respondents also asked if further process and methods development work is planned on existing use evaluations. Respondents also stated that the proposed update provides little additional detail beyond that in the interim late stage assessment statement, and that it is premature to publish final processes and methods for existing use assessment until the after-action learning and stakeholder feedback exercises are complete. Detail presented to the NICE Board on in July 2025 stated that learning from these 2 sources would be used alongside consultation comments to finalise the HealthTech Programme Manual. This approach was stated to lack transparency.

60. Respondents commented that the stakeholder engagement processes should be revised to ensure meaningful and timely input from industry representatives during committee discussions. They also stated that what was allowed or expected from companies during committee meetings was not always clear.

61. Respondents commented that it is important to understand how the selection of technologies to be evaluated is made and what is driving it. They stated that companies need early warning because a decision to no longer

fund could be devastating to the company if it happens quickly and orders dry up overnight.

Our response and any changes to the NICE HealthTech programme document

62. Introductory sections 4.1.1 and 4.1.2 in the existing use section of the manual have been updated to provide further background to the existing use guidance approach.

63. Consistent with assessments done for wider NICE guidance, the methodology for assessing cost effectiveness for existing use guidance considers technology price alongside impacts on health and resource use. Any higher prices for a technology can be justified by reductions in healthcare resources or benefits for people's health resulting from its use, which could result from any innovative new properties or use. Economic analysis does not just estimate the resource consequences of using a technology but evaluates costs in relation to benefits (including benefits to quality of life) and harm of alternative courses of action.

64. Considerations for decision making about recommendations for existing use guidance follows those set out in the section on overarching methods for HealthTech guidance, including views expressed by experts, including clinical experts, particularly their experience of the condition, current care and technology use in clinical practice, and the experience of people with lived experience of the condition (see sections 2.4 and 4.5). Experts are appointed for guidance topics to ensure that we have access to necessary experience and input for decision making. For existing use guidance, views from appointed experts are augmented by the user preference assessment to help identify any value offered by a technology that may not be captured in the health economic evaluation. Committees will also consider any information provided by stakeholders or other organisations (see section 1.3.9 in NICE HealthTech programme manual), for example experiential evidence from voluntary and community sector organisations. This is to reflect the experience of patients, healthcare professionals and commissioners of current

care in the NHS. It can also help understand the potential impact of using different technologies or features.

65. Section 4.5.6 of the proposed manual text explicitly states that factors related to technologies that are important for patients or healthcare professionals can be considered by committees when deciding what can be specified as important when choosing between technologies. Section 4.5.9 of the proposed manual text furthermore states that recommendations issued can include additional factors that the committee consider important considerations related to the technologies, including specifying an appropriate range of technologies that need to be available.

66. Future existing use assessments will be initiated after the updates to NICE HealthTech programme manual (PMG48) consulted on here are published. This includes updates to the proposed text made in response to the consultation comments received. The pilot topic after action reviews (AARs) have completed, and the feedback received has been considered in updating the manual text.

67. Section 1.5.4 of the NICE HealthTech programme manual describes the participation of company representatives at a committee meeting. Input from representatives from companies with technologies being evaluated at committee meetings for existing use guidance is consistent with participation across other HealthTech and wider NICE guidance topics. Representatives can attend the public session (part 1) of the committee meeting, and the chair will ask them to respond to questions from the committee and comment on any matters of factual accuracy.

68. NICE-wide topic prioritisation: the manual describes 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. This includes routing topics involving diagnostics, devices, digital technologies for HealthTech guidance. Decisions about what guidance will be developed in terms of the lifecycle approach to be used (for early, routine or existing use guidance) are finalised during scoping and included in

the final scope. This decision is made by NICE, considering feedback received during the scoping process, for example at scoping workshops. Section 2.1.28 in the proposed manual text describes further detail on this process, and principles that distinguish existing use guidance from early or routine use guidance. This section has been updated based on feedback received at this consultation (see section 1).

Section 11 – Existing use guidance recommendations

Summary of comments received

69. Respondents raised concern about the proposed recommendation that there is ‘not enough evidence to justify paying extra for any of the technologies or technologies with certain features or functions’. They stated that a limited evidence base does not equate to no justification for price differences, and that it is unclear how such a recommendation can be made in the absence of clear evidence.

70. Respondents suggested clarifying in recommendation wording that ‘there is not enough evidence to determine whether price differences are justified or not’. They also suggested amending the ‘what this means in practice column’ to adopt a more neutral tone, for example stating that based on the evidence gathered, there is currently no justification for paying extra, rather than implying that the technologies had been assessed as inadequate.

71. Respondents stated that if it appears over time that most technologies are receiving this recommendation, NICE must consider whether the existing use guidance is delivering valuable, workable advice to the NHS.

72. Respondents commented that it is important that guidance, as well as the manual, explains clearly what the different recommendations mean. Regarding the recommendation wording that there is ‘not enough evidence to justify paying extra for any of the technologies or technologies with certain features or functions’, respondents stated that while they were pleased that there is an explicit acknowledgement in the ‘What this means in practice’ column that there are factors that are not based in clinical or economic

evidence, but are highly relevant when choosing a technology, they had serious misgivings about how the headline recommendation will be interpreted. Taken out of context, it was stated as likely that the reader will give no consideration to such factors and examples of these should be detailed in the guidance.

73. Respondents stated that while price should always be a consideration, in circumstances where evidence is lacking or uncertain price should be one of several considerations, rather than the primary driver. This type of recommendation wording risks being interpreted by commissioners and procurement teams as an instruction to base decisions solely on price. This approach was stated to be in conflict with Value Based Procurement principles and as failing to acknowledge the broader dimensions of value, including patient experience and system impact.

74. Respondents stated that the proposed recommendations risk patients being offered sub-standard products which do not meet their needs or preferences, or those or the health care profession. They stated that the recommendations do not allow clinical appropriateness to be considered and that could lead to serious patient concerns as treatment decisions appear to be procurement, not clinically, led.

75. Respondents stated that patients require a wide choice of products to suit their individual needs. They suggested that recommendations include endorsement of a broad principle that a wide set of product choices should be maintained for individual needs to be considered.

76. Respondents asked whether a ‘do not use’ option for a recommendation should be added. They highlighted potential benefit if there are potential harms for patients.

77. Respondents stated that there needs to be more clarity about the term ‘least expensive’ which could be interpreted it could be viewed very differently from its intended meaning of lowest overall cost.

78. Respondents commented that demanding significant new data may create financial and commercial pressures that affect whether a company will continue to keep the technology available in the UK over the long term. They recommended that research requests be made only when strictly necessary, and that they focus on clinic-, centre-, or Trust-level real-world data or small studies, rather than large RCTs or extensive head-to-head comparisons.

79. Respondents asked for greater clarity on how sustainability elements will be considered.

Our response and any changes to the NICE HealthTech programme document

80. The manual sections on recommendations for existing use guidance (in sections 4.5.5 and 4.5.6) have been amended. This includes removing mention of justifiable prices from the recommendation headline in section 4.5.6. Instead, the recommendation now focuses on what to consider when choosing between similar technologies in existing use in the NHS. The 'What this means in practice' text for this recommendation further clarifies that there is not enough evidence of clinical or cost effectiveness to determine if any technologies can be recommended over other similar options or determine whether price variations between these options are justified or not. In addition, there may be further factors that could be considered when choosing a technology, that are specified in the recommendations.

81. NICE will consider the outputs of guidance over time and if any changes to approach are needed. NICE's Guidance Executive consider and sign off guidance and other products for publication.

82. As noted, the guidance recommendations are accompanied by an explanatory 'What this means in practice' section. In terms of factors that committee believe are important when considering which technology to use, these will be specified in the recommendations. An example is the recently published guidance on topical antimicrobial dressings for locally infected leg ulcers: late-stage assessment which included considerations in the recommendations (see sections 1.3 and 1.4) about which technology to use.

83. The price of a technology is not the only considerations in estimates of cost effectiveness used by NICE in decision making. See point 63 for greater detail on this point. For the perspective that NICE takes in decision making, see comments and responses in section 9.

84. Where the 'least expensive' technology is recommended, it is NICE's intention that this refers to the total cost of the technology and any supplemental costs (such as training or disposable parts) over its intended lifetime. Sections 4.5.6 has been amended to state that considerations can be based on "…price of the technologies and any additional costs associated with use, including a recommendation to use the least expensive option…" (underlined text added).

85. The manual text on recommendations for existing use guidance has been amended to include a section stating that in exceptional circumstances, a 'should not be used' may be made for technologies in existing use guidance, with references to further detail on this type of recommendation described elsewhere in the manual (section 2.4.21).

86. When describing research recommendations that can be made for existing use guidance, the manual text (in section 4.5.8) references section 2.4.28 which states that while the guidance can describe broader evidence that would be beneficial, the recommendations should focus on uncertainties that are essential to future decision making and are considered feasible to address.

87. How our guidance can support an environmentally sustainable health and care system is an active area of interest for NICE, as described on our Sustainability webpage. Findings from an options appraisal in 2023 reconfirmed that the data and analytical standards around environmental impact data about individual healthcare products are not yet sufficient for us to consider sustainability routinely in all NICE technology evaluations. However, we identified several potentially impactful activities worth further consideration in the short term. One such activity is being taken forward within our Health Technology Assessment Innovation Laboratory (HTA Lab). We're exploring

the feasibility of evaluating the environmental impacts of competing medicines or health technology products that have little or no expected difference in health or cost outcomes.

Section 12 – Evidence for existing use guidance

Summary of comments received

88. Respondents raised concern with the proposal that pragmatic or rapid review methodology and principles can be used in the literature review for existing use guidance, with specific components of the systematic review process either being restricted or omitted. They commented that this approach has been problematic and led to delays in guidance publication.

89. Respondents stated that NICE's expectation of available evidence for technologies in existing use in the NHS may be unrealistic. For many products in use the types of evidence NICE expects have not historically been needed and are therefore not available.

90. Respondents stated that the evidence base available should be looked at during prioritisation and NICE should not prioritise topics where they have already ascertained that the evidence base is weak or does not exist.

91. Respondents requested that if no evidence is identified that is directly relevant to the decision problem, this should be highlighted to manufacturers at the topic selection stage of the assessment, allowing them to provide additional evidence that could inform a decision to proceed with the assessment and subsequent scoping of the project.

Our response and any changes to the NICE HealthTech programme document

92. Section 4.3.5 of the proposed manual text, which described the potential use of pragmatic or rapid review methodology in the literature review for existing use guidance, has been amended to state that if such approaches are to be used, they must be agreed with NICE. This section also notes that justification and rationale should be described in the assessment protocol,

along with clear explanation of the components of the review process that have been restricted or omitted.

93. NICE-wide topic prioritisation: the manual describes 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. This includes potential existing use assessment topics. A prioritisation framework for decisions is described (in section 9), and criteria considered include evidence availability (see section 9.2). A driver of topic selection is the priorities of the health and care system, and what value will NICE add to the health and care system by producing guidance. Where several technologies are available, and the healthcare system has indicated that guidance would be beneficial to help make decisions about which to use, an absence of evidence to justify choosing a technology over another or to justify a higher price may be very relevant to decision making, so is not in itself a justification for not producing guidance. Existing use assessments can identify key areas for future evidence generation that could support future decision making (see section 4.5.8 in the manual).

94. Companies are asked to provide responses to requests for information from NICE as part of the assessment (described in section 1.3.4 in NICE HealthTech programme manual), which includes any evidence they consider potentially relevant. Section 4.3.2 of the proposed manual text states that, as part of evidence identification activities done as part of the evidence review, if no evidence is identified that is directly relevant to the decision problem, a broader evidence base may be considered. For example, evidence from the technology's use in a different population or setting.

95. To provide further support and guidance on prioritisation of studies for inclusion in an assessment report, NICE commissioned the NICE Decision Support Unit to produce a technical support document on 'Prioritising studies and outcomes for consideration in NICE HealthTech literature reviews'. This is referenced in section 2.2.11 of the manual (and is relevant for all guidance, including existing use guidance).

Section 13 – User preference and stakeholder input

Summary of comments received

96. Respondents questioned the statement in section 4.4.9 of the proposed manual text that the views of the users are subjective and are therefore not subject to factual accuracy checks. They stated that subjective comments should be subject to scrutiny, otherwise one opinion may be deemed sufficient evidence, and guidance would become opinion-based rather than evidence-based.

97. Respondents commented that the user preference assessment provides a strong route for patient voices to be heard and feel this is a step in the right direction.

98. Respondents asked how user experience will be considered and whether companies can provide user experience case stories. Also, that assessments should contain sufficient volumes of patient feedback in quality and quantity to provide representative conclusions, in addition to any standard assessment conducted. Respondents stated that future assessments should involve substantial and inclusive cohorts in user-preference exercises, ensuring that no patient groups are overlooked

99. Respondents recognised the challenges of ensuring users with experience of all technologies being assessed were included in the user preference work. But stated that it is important that there is representative input from people with experience of using all the technologies being considered.

100. Respondents stated that user preference is more beneficial when an appropriate sample size is considered. They commented that in pilot LSAs only a small handful of experts were included, which potentially introduces risk of bias and undervalues the impact a user preference study could have. Respondents also commented that larger, more representative cohorts should have been engaged for some LSA pilot topics.

Our response and any changes to the NICE HealthTech programme document

101. NICE involves people with lived experience (through our People and Communities Team) and other experts with experience of the treatment pathway in all assessments (see sections 1.3.10 to 1.3.17 in the NICE HealthTech programme manual for detail on expert involvement in the guidance production process). The user preference assessment is an augmentation of this expert engagement. It aims to establish if there are relevant considerations that are not captured, or fully captured, by the economic evaluation.

102. The output from the user preference assessment is used in the same way as expert opinion. As described in section 2.4.1 of the proposed manual text (referenced in section 4.5.1 in the existing use guidance section), the committee bases its recommendations on the evidence presented. This includes views expressed by experts, including clinical experts, particularly their experience of the condition, current care and technology use in clinical practice, and the experience of people with lived experience of the condition. The user preference assessment aims to gather views from a larger number of experts than would typically be available for early or routine use guidance. The output is particularly likely to inform decision making when there is uncertainty about the cost effectiveness of a technology, and if the user preference assessment provides a strong indication of value that has not been captured by the economic evaluation.

103. Section 2.1.24 of the proposed manual text notes that outcomes related to the needs and preferences of patients and healthcare professionals for different technologies, or particular functions or features of technologies, may be useful for decision making and can be specified in the scope. This may be more likely when there are multiple technologies defined as interventions in the scope, and evidence that compares clinical and system outcomes between these technologies is likely to be absent or weak. Section 4.2.1 has been updated to highlight that such outcomes may be particularly relevant to include in scopes for existing use guidance. Companies can include any

studies or data reporting such data in response to a request for information (see section 1.3.4 of NICE HealthTech programme manual). These may be considered by the external assessment group as part of their evidence review as per their project specific protocol.

104. NICE thanks the respondents for recognising the challenges in recruiting a sample of users with experience of all the technologies being assessed. Section 4.4.7 of the manual says 'Users are selected taking into account the NICE policy on declaring and managing interests for NICE advisory committees'. This states 'This policy supports a culture in which we are transparent about the interests of those who are members of, or work with, our advisory committees, so that the effect of interests is known, understood and managed. It aims to ensure that the advisory committees have access to the appropriate expertise on the areas under consideration, while minimising the risks to their perceived ability to objectively consider the evidence.'

105. NICE collects information on the devices that experts taking part in the user preference assessment have experience of, and reports this information for the committee to consider. While it may not be possible to obtain input from a group of experts that have experience of using every technology in an assessment, NICE will try and get as broad an experience of using the assessed technologies as possible. Additional text has been added to section 4.4.7 stating that the relevant experience of users will be considered in selection, including experience of using as broad an array of the assessed devices as possible. Aspects of the user preference work such as how many people were involved (sample size) are reported and available to committee to take into consideration when using the report in its decision making. The report also includes a section on possible limitations and biases.

106. The statement that 'Because the views of the users are subjective, they cannot be considered inaccurate' has been removed from section 4.4.9. However, to help groups submitting comments to understand how best to direct their responses, text has been added to clarify that 'The experts' opinions contained in the report on what is important to them about the technologies are not something that can be considered factually inaccurate'.

Section 14 – Scoping for existing use guidance topics

Summary of comments received

107. Respondents commented that it is unclear how NICE will or should act in scoping a product group that is in widespread use but that may include specific technologies that are not yet widely used. Respondents commented that they believed there is a need during scoping to assess the degree of innovation in the potential product pool. They stated that products judged as innovative should not be included in an existing use analysis.

108. Respondents commented on the statement in the proposed scoping section for existing use guidance (section 4.2.1) that the scope may not define a comparator. They stated that previous LSA guidance has suffered from a poorly defined standard of care, and that NICE should provide detail on how a standard of care or reference product will be selected in their analyses as this can be a major point of contention. Respondents commented that the scope must define a comparator, even if this is other interventions. Respondents also suggested this should be based on market share. Other respondents supported not defining a comparator, stating that a comparison with a legacy technology may have limited benefit for fast moving markets.

109. Respondents commented that a features based approach is not appropriate for some intimate and personalised products where a holistic approach to clinical, personal and environmental factors is needed.

110. Respondents asked for clarification on the value proposition for technologies assessed in existing use guidance. They stated that value propositions of interventions tend to compare with standard practice when the device is launched. It is unusual for devices to go head to head with each other as neither tend to be standard practice.

111. Respondents asked NICE to recognise that technologies should also have the same intended use as there may be anatomical considerations that make them unsuitable for the same identified population and therefore unsuitable for fair comparison.

Our response and any changes to the NICE HealthTech programme document

112. Section 2.1.28 has been updated to more clearly define the general principles used to define a topic as suitable for existing use guidance. Existing use guidance is intended to investigate groups comprised of similar technologies at least some of which would be considered established practice in the NHS. These technologies are likely to be differentiated by incremental innovations or continuous improvements, or are copycat technologies, as defined by the Department of Health & Social Care's Medical technology innovation classification framework. Technologies that offer potential transformative or disruptive innovation are more likely to be assessed for routine use guidance. The choice about which guidance lifecycle approach to take will be made by NICE but is strongly informed by feedback received during scoping, such as at a scoping workshop.

113. Comparators are defined as established practice in the NHS or are recommended in existing guidance from NICE or other bodies (see section 2.1.15). For existing use guidance, the group of technologies being assessed (that is the interventions) are considered established practice. The key consideration is comparison between technologies within this group. Existing use assessments therefore often make multiple comparisons between the different interventions, rather than with an independent comparator. Section 4.2.1 in the guidance states that the assessment may not define a comparator, not that a comparator will not be defined for every topic. This will be considered during the scoping period and input from stakeholders and experts will inform a decision about whether a comparator should be specified or not in the scope.

114. The option to define interventions as a group by shared features or functions (as described in section 4.2.1) will be considered during the scoping period, with the opportunities for stakeholders to provide information and input, for example at a scoping workshop, including if they think this approach is not suitable for the topic.

115. Section 4.2.1 has been amended to provide further clarification of a value proposition for products considered in existing use guidance. This should focus on how the interventions within a group of technologies differ and the potential impacts of these differences, such as on patient outcomes or healthcare resource use.

116. As for routine use guidance, existing use guidance will not be developed for technologies outside of their indication or intended purpose for use, as defined by any regulatory approval for use in the UK.

Section 15 – Economic evaluations done for existing use guidance

Summary of comments received

117. Respondents questioned the value of regression analysis to explain price variability, noting that it cannot inform if any price differences are justified. They also raised concern that it may give a very precise estimate that is taken as accurate and should not necessarily be routinely consider as suitable analysis.

118. Respondents also questioned the statement in the proposed manual text that exploratory analyses may be used to investigate potential justifications for price differences. They stated that such analyses will not provide a robust approach for making recommendations and are highly uncertain therefore it is crucial that this uncertainty is comprehensively communicated to committee members. Respondents also asked for further detail of such exploratory analyses.

Our response and any changes to the NICE HealthTech programme document

119. Reference to the use of regression analysis (section 4.4.4 in the proposed manual text) has been removed. External assessment groups can decide on a topic-by-topic basis if this analysis is useful and justify its use.

120. Further detail has been added to section 4.4.5 in the manual text to clarify that exploratory analyses may be used to investigate the feasibility of justifications for price differences or to help identify areas for future evidence generation. Further text has also been added to emphasise that the results of any exploratory analysis should be presented as such and with reference to uncertainty in any result generated. The committee can then be fully aware of this when considering whether and how much to consider exploratory analyses in its decision making.

Section 16 – Clarity on process and input from stakeholders for existing use guidance

Summary of comments received

121. Respondents stated that during the process of LSA guidance, expectations and requirements of stakeholders was not always clear enough. How stakeholder input was used was also stated to be unclear. Respondents stated that companies felt their concerns were undervalued, and they had limited opportunities to input.

122. Respondents also stated that there were challenges with tight deadlines to respond to requests from NICE, or comment on documents. Longer review periods were requested. Respondents also commented that some companies had several LSA topics underway at the same time, and this led to overlapping periods for consultation which created greater challenges for providing comments.

123. Respondents stated that the process of how topics are selected for existing use guidance is not clear and requested greater transparency.

124. Respondents highlighted the importance of getting input from people with lived experience as part of the guidance production process, and that there was a need for better inclusion of patient voices.

Our response and any changes to the NICE HealthTech programme document

125. The process for existing use guidance is now described in the NICE HealthTech programme manual (section 1: Processes for developing guidance in the HealthTech programme), which will be used for the development of future existing use guidance (that is, to replace the LSA interim process and methods statement). This has been developed to provide a clear path through the guidance production process, and to provide consistency across the guidance production process used in the NICE HealthTech programme. The manual text provides a summary overview of guidance development process (see table 1) which includes a summary of opportunities for stakeholder input at different stages in the process. The AARs have highlighted several areas for potential improvement in how we interact with companies in future existing use guidance topics. One such area is greater contact and communication with companies at the start of an assessment to make sure they better understand the process and how they can interact with NICE and the decision-making process. We are also developing a frequently asked questions document to share with companies.

126. A key goal for NICE is to produce timely guidance for the health and care system (for further detail see the NICE transformation plan). This means we need to set deadlines for receiving information so it can be appropriately considered by NICE, assessment groups or committees, as appropriate. We will make sure that dates of committee meetings and times for comments or information to be provided are indicated to companies and stakeholders as far in advance as possible to give time to prepare.

127. The issues of a company having technologies in several guidance topics underway at once has been noted and we will be mindful of this in the future and try as much as possible to avoid this occurring.

128. How topics are selected for NICE guidance and routed to the NICE HealthTech programme is described in NICE-wide topic prioritisation: the manual (see section 7.1.4 for topics that involve use of new health technologies). As described in section 1 of this document, decisions about

what guidance will be developed in terms of the lifecycle approach to be used (for early, routine or existing use guidance) will be made by NICE and included in the final scope. Section 2.1.28 of the manual provides further detail on this.

129. Making sure that the experience of people with lived experience is considered in guidance development is an important part of the process. NICE has a People and Communities team who support public involvement across NICE's work programme, helping to support the involvement of patients, carers, people who use services, and the organisations who represent them, throughout the evaluation. More detail can be found on the NICE website: People and communities - putting you at the heart of our work. Experts are selected to help committees develop guidance for existing use guidance topics, including people with a condition and their carers, who can provide information about the impact of both the condition and the technology being assessed. The process for identifying and selecting experts is described in NICE HealthTech programme manual (see sections 1.3.10 to 1.3.17). NICE can also invite non-company stakeholders or other organisations to provide evidence to inform scoping and the assessment. This can include qualitative, real-world and experiential evidence from voluntary and community sector organisations. This is to reflect the experience of patients, healthcare professionals and commissioners of current care in the NHS. It can also help understand the potential impact of using the new technology. Information on implementation issues, such as staffing and training needs, could also be provided.

130. Feedback received as part of the AARs has been considered alongside the consultation comments received and has been responded to in this report. In addition, a specific section (section 18) identifies key themes from the AARs and what we are doing in response.

Section 17 – Proposed updates to existing NICE HealthTech programme manual (PMG48) and Interventional procedures programme manual (PMG28)

Summary of comments received

131. Respondents commented that greater clarification would be beneficial about the scope of the NICE HealthTech programme manual (PMG48) and NICE health technology evaluations: the manual (PMG36).

132. Respondents questioned why some sections of text were being removed from the interventional procedures manual (PMG28).

133. Respondents questioned why text from sections in the existing HealthTech manual (PMG48) is being removed (from sections 2.1.14, 2.1.15 and 2.1.20).

Our response and any changes to proposed changes to the NICE HealthTech programme manual (PMG48) and Interventional procedures programme manual (PMG28)

134. Further text has been added to the introduction of the NICE HealthTech programme manual (PMG48) to clarify the purpose of manual.

135. Text that is proposed to be removed from the Interventional Procedures manual (PMG28) is to prevent duplication, because text on process to be used for Interventional Procedures (IP) guidance can now be found in the NICE HealthTech programme manual (PMG48) or elsewhere on the NICE website (such as information on Freedom of information). Section 1 of the NICE HealthTech programme manual (PMG48), which describes process for producing guidance in the HealthTech programme, states that 'The process set out here will also be used for developing interventional procedures guidance, superseding any process described in the interventional procedures programme manual' .Consultation will still be done on draft guidance produced for IP guidance, as described in the NICE HealthTech programme manual (PMG48), section 1.5.5.

136. Text from sections 2.1.14, 2.1.15 and 2.1.20 in the existing HealthTech manual (PMG48) is being removed to prevent duplication, because the information contained in these sections will be presented elsewhere in the updated PMG48 document (sections 2.3.28, 2.3.12 and 2.3.25, respectively).

Section 18 – Key themes from the after action reviews (AARs) held for the LSA topics

Feedback received as part of the AARs has been considered alongside the consultation comments received in the above responses and updates made to the manual text. This section provides an overview of the key themes identified from the AARs and what we are doing in response.

Key theme 1: Timelines

137. Respondents commented that the timelines for submitting evidence and reviewing documents from NICE were consistently too tight across all topics.

Our response

138. Similar points were raised in comments submitted on the manual consultation, as described, along with our responses, in section 16 (‘Clarity on process and input from stakeholders for existing use guidance’). We will make sure that dates of committee meetings and times for comments or information to be provided are indicated to companies and stakeholders as far in advance as possible to give time to prepare. When topics are selected for NICE HealthTech guidance by the NICE Prioritisation Board, this decision is stated on the NICE website (Our prioritisation decisions) to give as much indication as possible that guidance will be produced.

139. The process for existing use guidance is now described in the NICE HealthTech programme manual (section 1: Processes for developing guidance in the HealthTech programme), which will be used for the development of future existing use guidance (that is, to replace the LSA interim process and methods statement). So, scoping for example will follow the standard process, including the options to hold a scoping workshop, have a consultation on the draft scope (for between 5 and 20 working days), or

both. Assessment periods for future existing use guidance will also be longer than the previous LSA topics to allow for greater time to produce the assessment report.

Key theme 2: Topic selection

140. Respondents requested greater clarity on selection rationale and earlier notice periods for launching LSA evaluations.

Our response

141. NICE-wide topic prioritisation: the manual describes 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. This includes routing topics involving diagnostics, devices, digital technologies for HealthTech guidance. Decisions about what guidance will be developed in terms of the lifecycle approach to be used (for early, routine or existing use guidance) are finalised during scoping and included in the final scope. This decision is made by NICE, considering feedback received during the scoping process, for example at scoping workshops. Section 2.1.28 in the manual text describes further detail on this process, and principles that distinguish existing use guidance from early or routine use guidance. This section has been updated based on feedback received at this consultation (see section 1).

Key theme 3: Communication and expectations

142. Respondents stated that process expectations were unclear in the pilot topics, particularly around committee roles and expert recruitment.

Our response

143. As described in the responses set out above in section 16 (‘Clarity on process and input from stakeholders for existing use guidance’), the process for existing use guidance is now described in the NICE HealthTech programme manual (Section 1: Processes for developing guidance in the HealthTech programme), which will be used for the development of future existing use guidance (that is, to replace the LSA interim process and

methods statement). This provides further detail on the guidance production process, including identification and selection of experts (see sections 1.3.11 to 1.3.14).

144. The AARs have highlighted several areas for potential improvement in how we interact with companies in future existing use guidance topics. One such area is greater contact and communication with companies at the start of an assessment to make sure they better understand the process and how they can interact with NICE and the decision-making process. We are also developing a frequently asked questions document to share with companies.

Key theme 4: Evidence prioritisation

145. Respondents stated that there was a perceived dismissal of company-sponsored evidence and narrow prioritisation approaches to evidence.

Our response

146. Similar points were raised in comments submitted on the manual consultation, as described, along with our responses, in section 12 above ('Evidence for existing use guidance').

147. To provide further support and guidance on prioritisation of studies for inclusion in an assessment report, and help clarify approaches to this, NICE commissioned the NICE Decision Support Unit to produce a technical support document on 'Prioritising studies and outcomes for consideration in NICE HealthTech literature reviews'. This is referenced in section 2.2.11 of the manual (and is relevant for all guidance, including existing use guidance). Approaches to be taken for evidence included in the assessment report will be described in the assessment protocol produced for the topic (as described in section 1.3.28 in the NICE HealthTech programme manual). Companies are asked to provide responses to requests for information for existing use guidance topics (as described in section 1.3.4 the NICE HealthTech programme manual) which is an opportunity to make NICE aware of any evidence they consider relevant to the assessment for consideration in the assessment report.

Key theme 5: User involvement

148. Respondents stated that there was limited and unrepresentative user samples in the pilot LSA topics, and that future work requires broader engagement strategies.

Our response

149. Similar points were raised in comments submitted on the manual consultation, as described, along with our responses, in section 13 above ('User preference and stakeholder input').

150. NICE involves people with lived experience (through our People and Communities Team to enhance outreach) and other experts with experience of the treatment pathway in all assessments (see sections 1.3.10 to 1.3.17 in the NICE HealthTech programme manual for detail on expert involvement in the guidance production process). Engagement with potential experts begins at the scoping stage (as described in section 1.3.10 the NICE HealthTech programme manual) to ensure early engagement, but experts can also be selected later in the process if needed, for example, if gaps are identified in the knowledge and expertise needed by a committee.

151. The user preference assessment is an augmentation of this expert engagement and aims to gather views from a larger number of experts than would typically be available for early or routine use guidance, increasing the input of experts into guidance.

Key theme 6: Guidance impact risks

152. Respondents raised concerns about misinterpretation of the LSA guidance and that they considered there has been a focus on costs rather than on outcomes.

Our response

153. As described in section 11 above ('Existing use guidance recommendations') based on consultation comments received we have amended the recommendation wording for existing use guidance and provided further detail in the accompanying 'What this means in practice' to

clarify the meaning of the recommendations. As described in points 63 and 83 above, the price of a technology is not the only considerations in estimates of cost effectiveness used by NICE in decision making. NICE's Guidance Executive consider and sign off guidance and other products for publication.

154. NICE works with the NHS, patients and carers, healthcare professionals and organisations to help put our guidance into practice, for further detail see the NICE webpage on Implementation help and advice.