Classification: Official

MedTech Funding Mandate Consultation report

January 2021

Contents

Summary

The consultation on the MedTech Funding Mandate looked at how we could:

i) direct the NHS on which MedTech innovations are effective and likely to give quick returns on investment for the NHS

ii) ensure a more sustainable approach to addressing financial barriers to adopting MedTech technologies in the NHS.

We asked questions to support policy development. These are shown below with links to the responses:

i) what the selection criteria for devices, diagnostics and digital products[1] should be (as shown in Table 1 below) **[response]**

ii) whether we should launch the policy with a limited number of products [response][2]

iii) what the most effective procurement and reimbursement approaches would be [response]

iv) what implementation support would best support delivering innovations to patients [response]

v) whether, and how, NHS organisations should demonstrate compliance with the policy [response]

vi) what the most effective ways of monitoring and evaluating the impact of the policy would be [response]

Following consideration of the feedback we revised the proposed policy as follows:

- Due to the significant impact of COVID-19 following these consultations we delayed the launch of the MedTech Funding Mandate until 2021/22 meaning that NHS providers and commissioners would not be required to comply during 2020/21. The policy will come into effect on 1 April 2021.
- The technologies supported have been revised from three to four to include gammaCore which had its MTG published in December 2019.
- The criteria to be cost-saving within 12 months, although not supported by the majority of respondents, will be retained for the first year of the policy. From April 2022 this criteria will be lengthened to cost-saving within three years.

[1] Including whether the MedTech Funding Mandate should include digital innovations, subject to NICE publishing digital technology guidance.
[2] Meaning initial focus would be on those technologies that the NHS has a greater familiarity with the implementation requirements.

The consultation

We publicly consulted on a MedTech Funding Mandate policy (‘the policy') between 5 November and 18 December 2019. We received 107 responses to our online consultation. A breakdown of respondents by organisation type can be found in Appendix A.

The consultation looked at how we could:

i) direct the NHS on which MedTech innovations are effective and likely to give quick returns on investment for the NHS
ii) ensure a more sustainable approach to addressing financial barriers to adopting MedTech technologies in the NHS.

We asked questions on:

i) what the selection criteria for devices, diagnostics and digital products[3] should be (shown in Table 1)

ii) whether we should launch the policy with a limited number of products[4]

iii) what the most effective procurement and reimbursement approaches would be

iv) what implementation support would best support delivering innovations to patients

v) whether, and how, NHS organisations should demonstrate compliance with the policy

vi) what the most effective ways of monitoring and evaluating the impact of the policy would be.

[3] Including whether the MedTech Funding Mandate should include digital innovations, subject to NICE publishing digital technology guidance.
[4] Meaning initial focus would be on those technologies that the NHS has a greater familiarity with the implementation requirements.

As well as providing responses to the survey questions, most respondents qualified their view with free-text comments.

Table 1: Selection criteria for consultation

Policy criteria	Description
Effectiveness	Demonstrated through a positive NICE medical technologies guidance (MTG) or diagnostic guidance (DG)[5]
Cost-saving over 5 years	Over £1 million over five years for the population of England
Cost-saving in-year	NICE modelling demonstrates a net saving in the first 12 months of implementing the technology
Affordability	The NHS must be able to afford the innovation: the budget impact should not exceed £20 million in any of the first three years – if this is unlikely, we reserve the right to not include a technology in the MedTech Funding Mandate and/or to undertake further commercial negotiations with manufacturers

We received a relatively poor response to our questions about procurement and reimbursement arrangements, implementation support, monitoring and evaluation (questions 10 to 13). This was in large part because a technical error meant responders did not have the option to select their level of agreement for these proposals when we launched the consultation. We fixed the error as soon as we became aware of it and sent a form to each respondent who had encountered the error. However, we did not receive a large response to the form. Through subsequent engagement activities, some stakeholders told us the subject matter was not applicable to them and/or their organisation, and others that they had chosen to focus their feedback on the core policy criteria.

We also held two stakeholder workshop events:[6] 57 people attended, and table discussions focused on the same questions asked in the online discussion.

We would like to thank all the individuals, patient groups and organisations that contributed to this consultation.

[5] For the 2020/21 MedTech Funding Mandate, the proposed cut-off for having a published NICE MTG or DG was 30 June 2019.
[6] Events held in London on 16 December 2019 and in Leeds on 18 December 2019.

Response to the consultation

Identifying the criteria for mandating technologies

Question 1: To what extent do you agree with the proposal to mandate compliance with NICE medical technologies guidance (MTGs) and diagnostic guidance (DGs) for innovations that meet the criteria for the MedTech Funding Mandate?

72% of respondents supported[7] mandating the use of innovations with a positive NICE MTG or NICE DG; 19% did not[8] (see Appendix B). Strongest support came from NHS providers and industry, and Clinical Commissioning Groups (CCGs) and Commissioning Support Units (CSUs) expressed the highest level of disagreement.

- Key reasons for supporting this selection criterion were that NICE has stringent and robust processes, and that without it being mandated, uptake of innovations would likely be lower – based on experience from publishing guidance alone.
- CCGs and CSUs suggested it would reduce their freedom to make local decisions and that NICE cost analyses were not always consistently presented.

> "Adoption of evidence-based innovations which deliver cost-effective improvements in patient care has to be the correct direction of travel. There have been 11 policy guidance documents providing routes to spread innovations in the NHS in the last eight years, yet the spread of innovation remains lacking in England. Given this, it may be time to apply a more prescriptive approach, as described in the consultation document." (NHS provider)

Our response

1. The proposal to mandate compliance with NICE MTGs and DGs for innovations meeting the MedTech Funding Mandate criteria will be adopted, to demonstrate their **effectiveness**.

2. The 2021/22 policy will cover four products that have met the criteria: HeartFlow FFRCT, PlGF-based testing, SecurAcath and gammaCore.

[7] For this consultation we define supporting as 'agreeing or strongly agreeing'.
[8] For this consultation we define not supporting as 'disagreeing or strongly disagreeing'.

3. The MedTech Funding Mandate criteria will apply from 1 April to 31 March each financial year.

4. The MedTech Funding Mandate will be updated and published on the NHS England and NHS Improvement website before 1 April each year.

5. To support longer term planning for the NHS, we will review NICE MTGs and DGs throughout the year and publish a list of technologies likely to meet the MedTech Funding Mandate on a quarterly basis, from June 2021, on the NHS England and NHS Improvement website.

6. To support local planning, we will also publish the draft list of innovations to be covered by the MedTech Funding Mandate alongside NHS England and NHS Improvement's operational planning guidance (usually published between November and January).

7. We are working with NICE to support their ongoing assessment of the resource impact process.

Question 2: To what extent do you agree that the MedTech Funding Mandate should cover digital innovations when the digital technologies guidance becomes available?

72% supported the inclusion of digital technologies as well as devices and diagnostics; 16% did not (see Appendix B). Strongest support came from NHS providers and industry, and weakest from CCGs and CSUs; they again expressed concern about central funding and loss of local decision-making.

> "It is evident that digital investment doesn't get the financial support and attention it needs, and this is a way to encourage commissioners and providers to prioritise it." (Other, AHSN)

Our response

1. NICE no longer considers digital technologies under a separate category of guidance; they are now evaluated through established routes such as MTGs or DGs. Therefore, digital technologies with MTGs or DGs will be reviewed using the processes outlined in question 1 and provided with the same support if they meet the criteria of the policy.

Question 3: To what extent do you agree that the MedTech Funding Mandate should only cover innovations that deliver material savings, i.e. over £1 million over five years for the population of England?

Almost half the respondents (47%) supported the criterion that the technologies should **deliver material savings to the NHS**, with the innovation required to save over £1 million over five years for the population of England; 32% did not (see Appendix B). There was highest agreement from CCGs and NHS providers.

- Key reasons for supporting this selection criterion were that many clinically effective innovations would meet this £1 million threshold and that it was a reasonable to include this for the first year. It was recognised across respondent types that having a defined minimum savings criterion is sensible and that £1 million was reasonable. Some suggested that this could be reviewed in future years.
- Key reason for not supporting this selection criterion were that it could be too restrictive; that the £1 million threshold should be lowered; that the threshold should be increased to focus on innovations that could deliver greater savings.

> "This seems a reasonable initial threshold and can always be adjusted in future years depending on the number of technologies with positive guidance being accepted / rejected from the mandate." (Industry)

Our response

1. We will include this criterion in 2021/22.

2. From April 2022 we propose removing this criterion to focus on a longer time horizon for net savings.

Question 4: To what extent do you agree that the MedTech funding mandate should only cover innovations that are likely to deliver net savings in the first 12 months based on NICE assessments?

Reaction to the **cost saving in-year** criterion was mixed; 46% disagreed with limiting the MedTech Funding Mandate to innovations that deliver saving in the first 12 months (as demonstrated by NICE modelling), while 40% agreed (see Appendix B). CCGs expressed the highest level of agreement.

- The key reason for supporting this selection criterion was that limiting the MedTech Funding Mandate to these technologies would reduce financial risk for commissioners.
- The key reason for not supporting it was that, without making reference to the innovations in the consultation document that met this criterion, 12 months was too short a time for an innovation to demonstrate financial benefits. This could discriminate against patients with certain diseases, where significant savings might be realised over a longer term, and it could introduce several perverse incentives, such as gaming and the distortion of investment decisions.

> "This criterion biases the mandate – for no good reason – in favour of technologies whose pathway efficiencies happen to fall earlier after their use. This will disincentivise companies with products whose downstream benefits fall outside the 12-month time horizon' (Other, independent healthtech consultant)

Our response

1. At the earliest possible opportunity, beginning during 2021, recognising the lower level of support for this criterion and that a longer time period would be more useful for planning by NHS organisations, the criterion will change to needing to deliver net savings in three years.

2. We will issue a signalling document, setting out the additional innovations captured by the three year criterion and with accompanying support to providers to adopt these as soon as possible.

Question 5: To what extent do you agree that the budget impact of innovations covered by the MedTech funding mandate should not exceed £20 million in any of the first three years?

43% supported using £20 million as an affordability threshold to exclude innovations or trigger extra commercial negotiations with suppliers should anticipated costs across England exceed that in any of the first three years; 22% did not. Highest opposition came from those recognised as 'other' and industry.

- Key reasons for supporting this selection criterion were that it was realistic, sensible and feasible to keep the option of limiting the MedTech Funding Mandate to these affordable technologies and that it was consistent with the 'budget impact test'[9] approach used by NICE for products undergoing a

[9] Further details of NICE's budget impact test are available here.

NICE technology appraisal. As in responses to question 4, some respondents wanted improvement in patient experience to be recognised along with cost savings.

- The key reason for not supporting it was that the criterion could limit innovations that would deliver significant savings but require investment above this threshold to do so.

Our response

1. For NICE technology appraisals, suppliers of technologies above this 'budget impact test' may be invited to additional commercial negotiations. To take a consistent approach we will include this criterion but reserve the right to have further commercial negotiations with suppliers or, to not include technologies in the MedTech Funding Mandate that breach this threshold.

This approach ensures that technologies supported by the mandate do not cause undue financial burden on the NHS, Question 6: To what extent do you agree with the proposal to limit the scope of the MedTech funding mandate to innovations previously supported by the Innovation Technology Tariff/ Innovation Technology Payment (ITT/ ITP) and with a published NICE guidance in 2020/21?

43% supported limiting the MedTech Funding Mandate to products previously covered by the ITT/ ITP programmes; 32% did not (see Appendix B).

i) The key reason for supporting this approach was that it was a good place to start as there was more reassurance about these products given the NHS' experience of implementing them.

ii) The key reason for not supporting it was the speed of transition from the ITT/ITP to this policy, which could reduce the impact of the technologies previously supported through those programmes.

> "The current ITP products have to a large degree been adopted already, again limiting the impact of the funding mandate and truly testing the policy." (Other, AHSN)

Our response

1. We will implement this criterion for the first year of the MedTech Funding Mandate; it is met by the four included products: HeartFlow FFRCT, SecurAcath, PlGF-based testing and gammaCore.
2. For the 2022/23 MedTech Funding Mandate this criterion will be removed to extend the scope of products that can be supported.

Summary of criteria to be adopted

Technologies that have their MTG or DG and this has been published up to and including the 30 June 2021 will be reviewed to identify any devices, diagnostics and digital products that:

i) **are effective**: demonstrated through a positive NICE MTGs or DG[10]

ii) **deliver material savings to the NHS**: the benefits of the innovation are over £1 million over five years for the population of England

iii) **are cost-saving within three years**: NICE modelling demonstrates a net saving in the first three years of implementing the technology

iv) **are affordable to the NHS**: the budget impact should not exceed £20 million, in any of the first three years.[11]

We will complete this analysis by October 2021 and announce the additional technologies that will be covered by the policy from 1 April 2022.

Question 7: To what extent do you agree that the savings calculations should include both 'cash releasing' and 'non-cash' releasing' savings?

79% supported this proposal; 9% did not (see Appendix B).

[10] More information on MTGs and DGs can be found here https://www.nice.org.uk/guidance
[11] We reserve the right to not include a technology in the MedTech Funding Mandate and / or to undertake further commercial negotiations with manufacturers if we believe the £20m cost limit will be exceeded in any of the first three years

- Key reasons for supporting this proposal were that it was a sustainable approach as non-cash releasing savings are considered to be as beneficial as cash releasing savings and their inclusion is essential for long-term sustainability an innovation's adoption; and non-cash releasing savings could recognise innovations that lower waiting times, improve efficiency and improve patient outcomes and experience.

> "'The inclusion of both types of savings is crucial to the assessment of interventional devices in ensuring they are supportive to the long-term goals of the NHS, whether through workforce, total system costs or pathway re-design' (Drug and device manufacturer, respondent type 'industry')

- The key reason for not supporting this proposal was that non-cash releasing savings could be difficult to monitor.

Our response

1. Both forms of savings will be included for the 2021/22 MedTech Funding Mandate and both forms of saving will be recognised.
2. During 2021/22 we will work with NHS England and NHS Improvement's Costing Team to develop the methodology to identify the use of the supported products in the Approved Costing Guidance standards. This will enable NHS providers to understand the non-cash resources saved at a local level.

Contracting mechanisms

Question 8: To what extent do you agree with the proposal to use NHS England and NHS Improvement guidance and inclusion in the NHS Contract as the main mechanisms for implementing the MedTech funding mandate?

64% supported this proposed approach; 16% did not (see Appendix B). Overall, CCGs disagreed with this proposal.

- The key reason for supporting this approach was that it was the best mechanism to ensure a standard approach to implementing the MedTech funding Mandate policy.
- The key reason for not supporting it was that commissioners have their own prioritisation

> "This pathway seems to be the most efficient pathway to seamlessly providing new technology that benefits patients, doctors and the health economy." (NHS acute provider)

processes and should be responsible for making funding decisions for their population.

Our response

1. We will retain the proposed new terms relating to the policy the final NHS Standard Contract for 2020/21.
2. We consulted on changes to the NHS Standard Contract in January 2019 and proposed this wording in regard to the MedTech Funding Mandate: 'The Parties must comply, where applicable, with their respective obligations under, and with recommendations contained in, MedTech Funding Mandate Guidance'.
3. 86% of respondents were in favour of including this wording and it was published as a new requirement of the 2020/21 contract in March 2020.
4. The NHS Standard Contract was replaced by temporary guidance for the first quarter of 2020/21, in response to COVID-19. This guidance advised against progressing new local contracts for the period April to July 2020, which will have included agreements relating to the MedTech Funding Mandate. As a result, we decided to delay the 2020/21 policy, and there is no expectation for the requirement in NHS Standard Contract to be enacted until 1 April 2021/22.

Minimising burden on the sector

Question 9: To what extent do you agree with the proposal to pilot the MedTech funding mandate policy with a limited number of products in the first year?

68% supported an approach that limits the number of technologies launched in the first year of the policy; 17% did not (see Appendix B).

The key themes in the responses that emerged from the proposal were:

- Respondents commented that piloting the policy with a limited number of products was reasonable place to start.
- Some indicated that limiting the number of products covered by the policy in the first year was too risk averse. They considered we would learn more from implementing a wider range of products.

Our response

1. We will proceed with plans to pilot the MedTech Funding Mandate with four products for 2021/22. This will ensure we can effectively monitor uptake and evaluate the success of the policy.
2. In 2022/23 we will remove the criterion that the product must have been previously supported through the ITP programme, as proposed in the consultation. A broader group of products will then be eligible for selection.

Procurement and reimbursement

Question 10: To what extent do you agree with the proposed procurement and reimbursement arrangements for innovations that will be covered by the MedTech Funding Mandate policy in 2020/21?

The number of responses to this question were low (40%). Respondents generally supported the proposed procurement, with products being made available via NHS Supply Chain to reduce the procurement burden on NHS organisations. There was a lower level of support for the reimbursement approach about the financial burden on NHS providers if they did not receive funding from their commissioner to use the products (21% supportive and 7% not supportive see Appendix B). Those attending our consultation engagement events did not support the use of a nominated supply cost, noting that this had not been used on an NHS Supply Chain framework previously.

- The key reasons for supporting the approach was that using NHS Supply Chain would provide a consistent national approach to implementing these technologies.
- The key reason for not supporting it was that it would not always be clear which organisation would be the primary financial beneficiary. This could create a barrier to adoption rather than removing one. Concerns were also raised about the use of a reference price, with some noting that suppliers may not agree to their prices being published.

> "The NHS Supply Chain route is supported although a transparent and simple reimbursement process is required." (NHS acute provider)

Our response

1. The products selected for the 2021/22 MedTech Funding Mandate are being progressed onto NHS Supply Chain systems and will be available to buy at nationally negotiated prices.

2. Given the relatively low level of support for the reimbursement approach in this consultation, and the highlighted difficulty in establishing which organisation is the primary financial beneficiary, we consulted on the revised approach of adding technologies covered by the mandate to a new excluded category of technologies as part of the updated National Tariff Payment System (NTPS).[12]

   This would mean that commissioners would pay for the technologies unless there was a significant planned tariff change. 68% of respondents supported this approach.

   Therefore the MedTech Funding Mandate states that the responsibility of clinically appropriate use of the technology is the providers duty, and funding of the technologies is the commissioners responsibility.

   Compliance with these responsibilities would be a condition of the NHS Standard Contract.

3. We also consulted on this through the NHS Standard Contract[13] consultation. 86% of respondents were in favour of the proposal to include the new requirement in the contract: that compliance with the MedTech Funding Mandate policy is a requirement for NHS providers and commissioners. Section 2.3 has been added to the Regulatory Requirements in the NHS Standard Contract 2021/22.

4. More information on the NHS Standard Contract and NTPS consultations can be found in Appendix C.

5. In addition, there is the option of setting a reference price, however we have not done so for 2021/22 and any plan to do so in the future will be consulted on. Local adoption of these innovations will be supported by the Academic Health Science Networks (AHSNs) and the Pathway Transformation Fund,

[12] The 2020/21 National Tariff Payment System guidance is delayed due to the impact of COVID-19. The consultation document can be found here.
[13] https://www.england.nhs.uk/nhs-standard-contract/20-21/

and we will monitor data on the use by NHS sites of innovations provided by suppliers.

Implementation, monitoring and evaluation

Question 11: To what extent do you agree with the implementation support which is proposed to be provided for innovations covered by the proposed MedTech Funding Mandate Policy?

47% agreed with this implementation support, 4% did not. However, a substantial number did not respond to this question (40%) (see Appendix B).

- Key reasons for supporting this proposal were that AHSNs are well placed to support the adoption of these innovations, but it was noted that they must be adequately resourced to do so. Many commented that the pathway transformation fund should be available for the MedTech Funding Mandate products.
- Reasons for not supporting it included querying whether AHSNs were close enough to the front line to support this implementation.

Our response

1. The Academic Health Science Network (AHSN) will support NHS providers, commissioners and suppliers with implementation. They have supported the NHS ITP programme since 2018 and have dedicated teams with the knowledge and expertise to assist in managing the roll out of innovation. They are familiar with the products selected for the 2021/22 MedTech Funding Mandate and have established relationships with NHS providers and commissioners.
2. This support will be supplemented by that from NICE as part of product MTG or DG guidance.[14] Resources include:
    - costing and resource impact reports
    - resource impact templates to help organisations assess the financial impact to them

[14] https://www.nice.org.uk/guidance/mtg34/resources
https://www.nice.org.uk/guidance/MTG32/resources
https://www.nice.org.uk/guidance/dg23/resources

- general implementation materials outlining how to put guidelines into practice.

Question 12: To what extent do you agree with the proposed monitoring process?

41% supported the approach to monitoring uptake of the innovations on the policy through a scorecard, Care Quality Commission (CQC) inspections, manufacturer uptake data and NHS Supply Chain uptake data; 7% did not. However, a substantial number of respondents did not answer this question (40%) (see Appendix B).

- Key reasons for supporting this proposal were that monitoring uptake and outcomes were important to understanding the impact of the policy. It was also highlighted that NHS Supply Chain uptake data would provide greater accuracy on the uptake of the policy.
- Key reasons for not supporting it were that supporting outcome data measurement could be an administrative burden for suppliers.

> "MedTech mandated technologies should be included in the innovation scorecard so that their uptake is closely monitored. Where the primary route to market is through NHS Supply Chain, NHS Supply Chain should be required to provide accurate sales data in addition to the manufacturer's own data." (Industry)

Our response

1. In 2021/22 we will monitor uptake data using a number of sources, including supplier data, NHS Supply Chain data and relevant national datasets.

2. We will use this data to update the innovation scorecard and regularly report progress to the Accelerated Access Collaborative Board.

3. For 2021/22 the policy will require no additional reporting requirements, so as not to disproportionately burden NHS providers and commissioners in the wake of the COVID-19 pandemic. However, during 2021/22 we will assess whether the suggestions we received about how compliance could be demonstrated to further refine the policy in 2022/23, and consult further, as required.

4. During 2021/22 we will work with NHS England and NHS Improvement's Costing Team to develop the methodology to identify the use of the supported products in the Approved Costing Guidance Standards. This will enable us to monitor activity from 2022/23.

Question 13: To what extent do you agree with the proposed evaluation process?

48% supported our approach to evaluating the policy during the launch year and to revaluating the policy for future years, taking into account the impact on patients and providers, and whether real world benefits are seen in the NHS; 6% did not. However, a significant number did not answer this question (see Appendix B).

- The key reason for supporting this proposal was that evaluating the uptake could provide insight into how the policy should be developed to maximise uptake.
- The key reason for not supporting it was that patient involvement in the evaluation was not outlined.

> "Three evaluation criteria are proposed in the consultation. These seem reasonable and proportionate in scope. As the more detailed evaluation framework is developed, a particularly high weighting should be attached to outcomes that matter most to patients. This will mean ensuring that patients are asked about their outcomes during the implementation and compared to previous cohorts who did not have the benefit of accessing the innovation during their care." (Representative body – NHS)

Our response

5. In 2021/22 we will monitor whether the clinical and financial benefits detailed in the NICE assessments are being delivered in real-world settings and assess the implementation impact on NHS providers and commissioners through setting up working groups, reviewing case studies, and continuing to work closely with and share learning through the AHSNs.
6. We will use this knowledge to improve support materials and adapt the policy in future years to further support the adoption and spread of these innovative technologies.
7. We will continue to engage closely with Patient and Public Voices to evaluate the impact of the policy on patients and learn from lived experiences.
8. We are launching the policy in 2021/22 with the five criteria proposed. There will be no additional reporting requirements for this year, so as not to

disproportionately burden NHS providers and commissioners in the wake of the COVID-19 pandemic. However, during 2021/22 we will assess whether the suggestions we received can be used to further refine the policy in 2022/23 when the criteria will have been reduced.

Findings from qualitative questions

Reference price vis a vis nominated supply cost

1. There were mixed opinions across respondent types as to whether nominated supply cost or reference price was the preferred approach for pricing. Some respondents commented that ‘this should be agreed on a case by case basis depending on the technology and the number of suppliers involved’. Those who favoured reference price, commented that ‘commissioners prefer using a ‘reference price that incentivises providers, with a requirement for providers to share details of any deals they have negotiated’.

2. Some respondents commented on whether nominated supply costs would be an effective mechanism as it has ‘not been used previously for this type of policy and may require each commissioner to agree a local framework’.

3. As reference prices need to be published it was also suggested that this may be a barrier to some manufacturers entering the NHS due to the ‘potential global pricing impact of a public reference price’ and that this could be mitigated by ’making a reference price optional’.

Compliance

4. Respondents comments have been summarised below. Although there was no consensus opinion on a single compliance approach, the following were suggested:

    - patient reported outcome metrics
    - patient surveys to collect patient experience metric data
    - clinical audit data
    - the use of clinical pathways - through commissioner guidelines and by providing and recording in-depth data of the uptake of innovation
    - manufacturers of technologies to have access to a whistle-blower scheme to flag providers that are non-compliant

- use of routinely collected data (e.g. HES) to collect uptake metrics.

Monitoring and evaluation

5. Some of the key suggestions for monitoring approaches were:

- audit patient outcome data, post usage of the innovation
- manufacturers to audit the level of sales and services provided to the NHS
- financial impact; both 'cash releasing' and 'non-cash releasing' data
- clear criteria set for expected outcomes post usage; however, outcomes should be set against real-life evidence which can be measured
- ensure there is an adequate baseline for comparison.

6. Some of the suggestions for evaluation approaches were:

- Evaluation should clearly outline which elements of the funding mandate are being measured;
- Real-world validation approaches should be developed by the AHSN;
- Both qualitative and quantitative feedback, including cost-benefit analysis;
- Care pathway analysis

Implementation

7. Some of the suggestions for implementation approaches were:

- Appropriate training of frontline staff involved in delivering the innovation, to enable immediate adoption
- Enough time and resource to adapt clinical pathways if required
- Allowing more time to transition from the ITT / ITP to the MedTech Funding Mandate to enable a smoother transition period
- Appropriate financial levers in place (reimbursement and procurement) to enable uptake and adoption.

8. The process that will be implemented in 2021/22

9. We have carefully considered each of the suggestions made through the consultation. For 2021/22 there will be no additional requirements included in

the policy, so as not to disproportionately burden NHS Providers and Commissioners in the wake of the COVID-19 pandemic. However, during 2021/22 and 2022/23 we will assess whether the suggestions can be used to further refine the Policy for 2023/24 and consult on any material changes.

Key messages and themes from stakeholder workshops

10. The main comments arising from the table discussions are grouped below:

- **Strong support for the MedTech Funding Mandate** and there should be no delay in implementation
- **Financial uncertainty in the provider sector** attendees suggested that we should add all the mandated products to the Innovation List that excluded them from the National Tariff, not just commissioner saving products to reduce financial pressure on the provider sector
- **Concerns that some of the criteria are too restrictive,** due to the mandated products only being chosen from the ITP pool for the first year and products needing to deliver savings within the first 12 months.
- **Phased transition from ITP Programme,** a more phased approach should be taken to ending the Innovation and Technology Payment (ITP) Programme, as a rapid transition could have a negative impact on access to ITP products that are not included in the mandate. We have carefully considered this feedback and will investigate the possibility of continuing financial support for ITT / ITP products not covered by the MedTech Funding Mandate or reimbursed through the tariff, subject to the absence of a negative NICE MTG or DG, through to the end of March 2021.
- **NICE methods consistency,** NHS England and NHS Improvement should collaborate with NICE to develop a standard specification for NICE evaluations, in particular the methods for cost analysis, to avoid any products being disadvantaged by the process
- **Robust monitoring and evaluation,** it is important that ongoing robust monitoring and evaluation is carried out to measure the success of mandated products. There was clear support for treating 2020/21 as a ‘pilot’ year and using the evaluation of the Policy impact to inform future years, particularly for the criteria and implementation support. Additionally, there

was agreement that evaluation should not be limited to financial benefits with the evaluation of patient outcomes and patient experience seen to be essential. As the three initial mandated products have been chosen from the ITP pool it is important that those who have already adopted the products are monitored and evaluated.

Responding to the consultation outcome

11. Taking account of the feedback received from the consultation, NHS England and NHS Improvement will now begin the implementation phase during which time the Policy and guidance will be further refined and published in December 2020. The Policy will come into effect on 1 April 2021.

12. Due to the significant impact of COVID-19 following these consultations we:

    i) delayed the launch of the MedTech Funding Mandate until 2021/22 meaning that providers and commissioners will not be required to comply during 2020/21;

    ii) will publish the MedTech Funding Mandate Guidance and update on our plans to further refine the Policy during 2020/21.

13. When the Policy is launched in 2021/22, all partner organisations and Patient and Public Voices will continue to work together and engage with key stakeholders as this work progresses. There are opportunities for refinement and testing of the Policy proposals during the pilot phase; to do this, we will work closely with providers, commissioners and Patient and Public Voice Representatives to ensure that the Policy is achieving its ambition to accelerate the uptake of selected NICE approved cost-saving medical devices, diagnostics and digital products in the NHS.

14. We will continuously review the MedTech Funding Mandate during 2021/22 and consult on any material changes for 2022/23.

Equality and health inequalities considerations

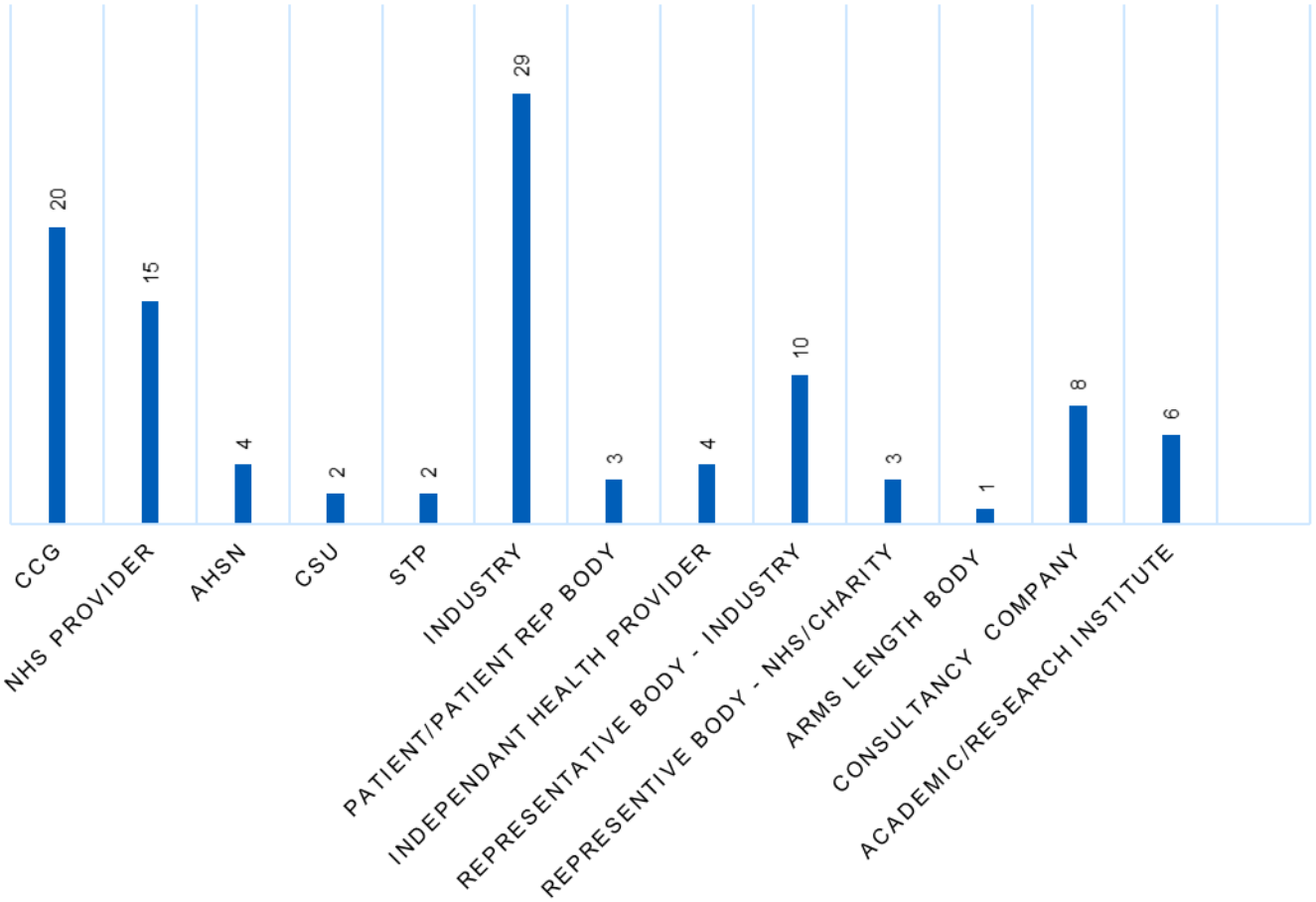
Consultation provides the opportunity to gather information on any health inequalities that could arise as a result of new or changed processes for making decisions about health services that are directly commissioned by NHS England and NHS Improvement.

We consider the MedTech Funding Mandate will have a positive impact by increasing the uptake of affordable innovations.

The data on increased adoption and spread will be fed into an Equality and Health Inequalities Analysis on this programme of work.

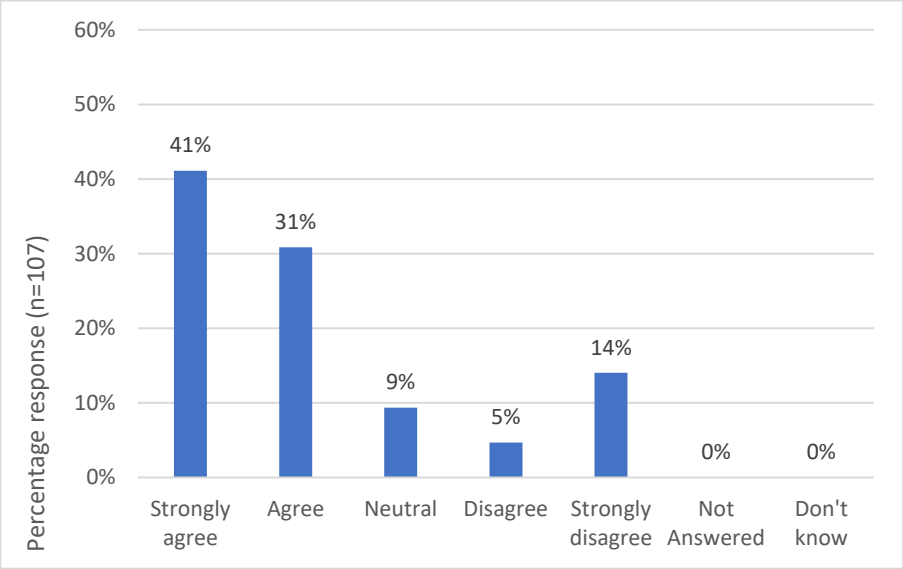
Appendix A: Respondent types

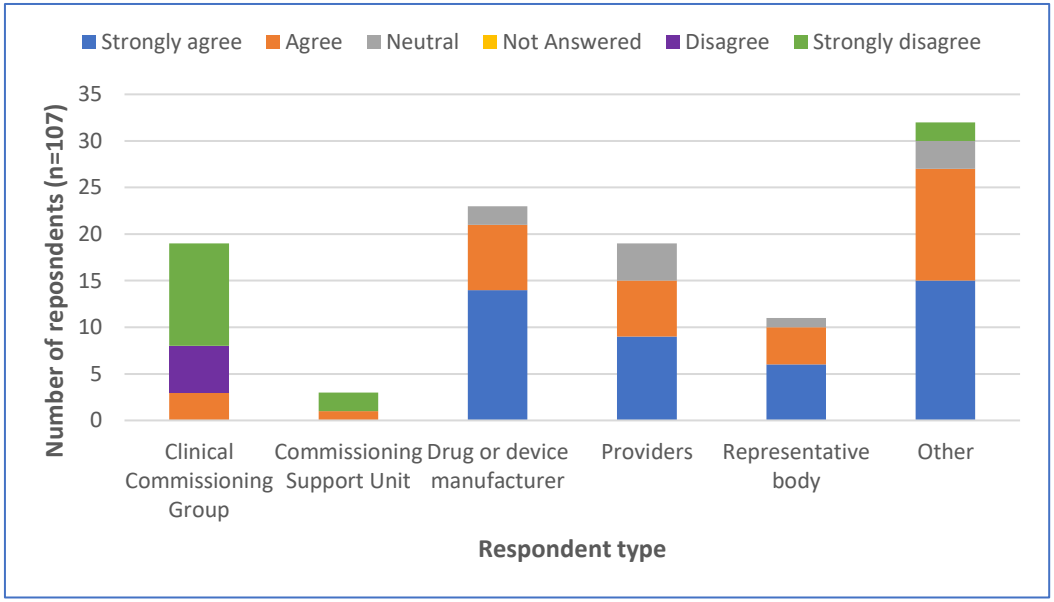
Figure 1: Breakdown of respondents by organisation type



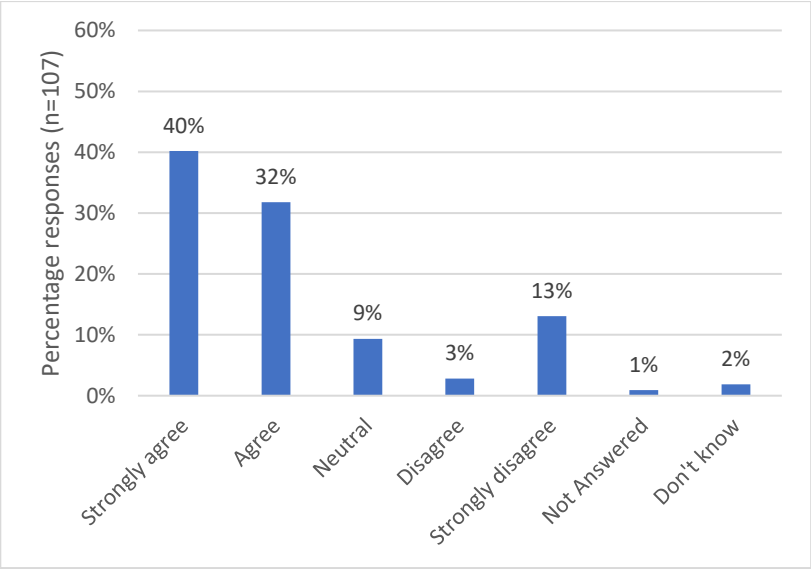
Appendix B: Consultation results

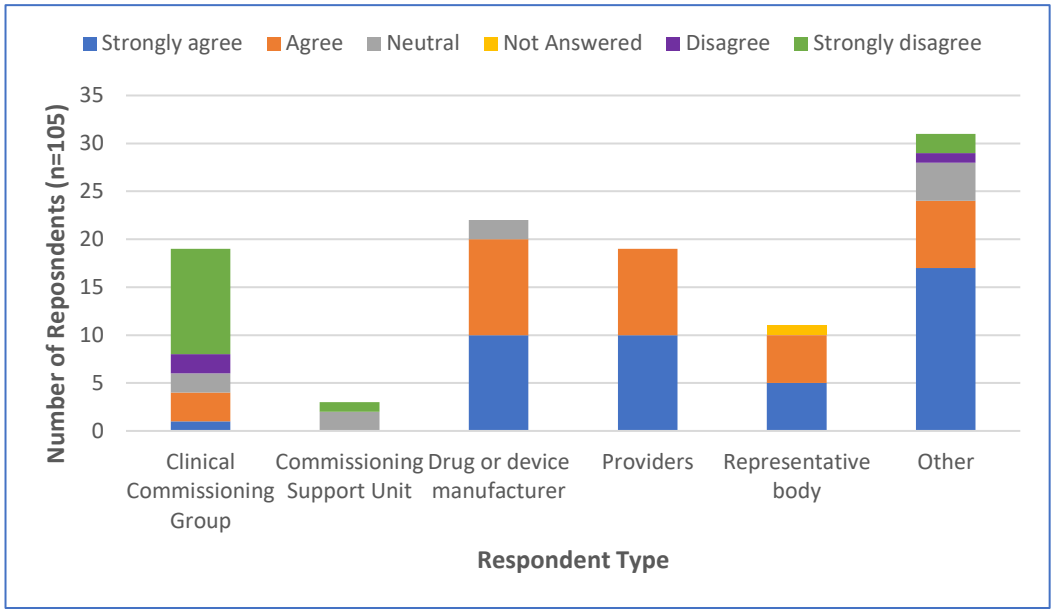
Question 1. To what extent do you agree with the proposal to mandate compliance with NICE medical technologies guidance (MTGs) and diagnostic guidance (DGs) for innovations that meet the criteria for the MedTech funding mandate?



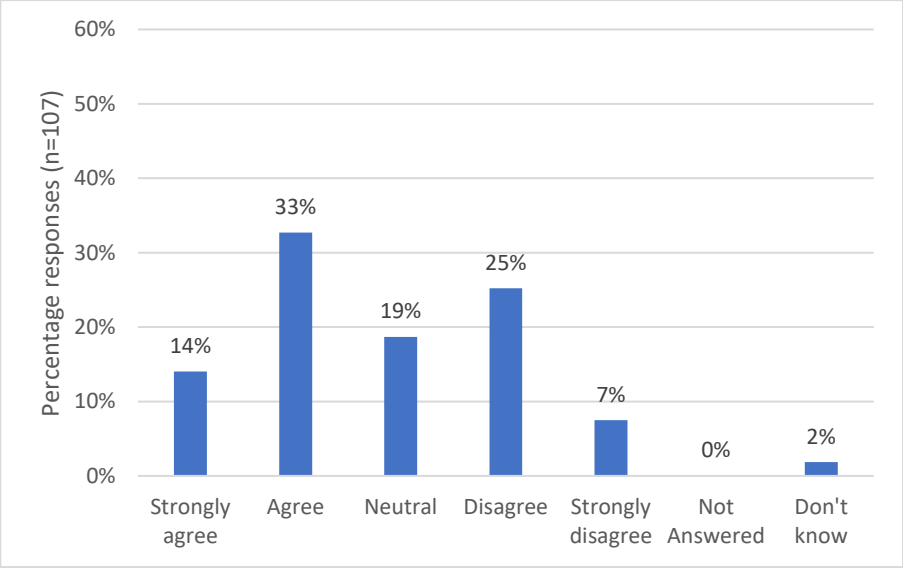


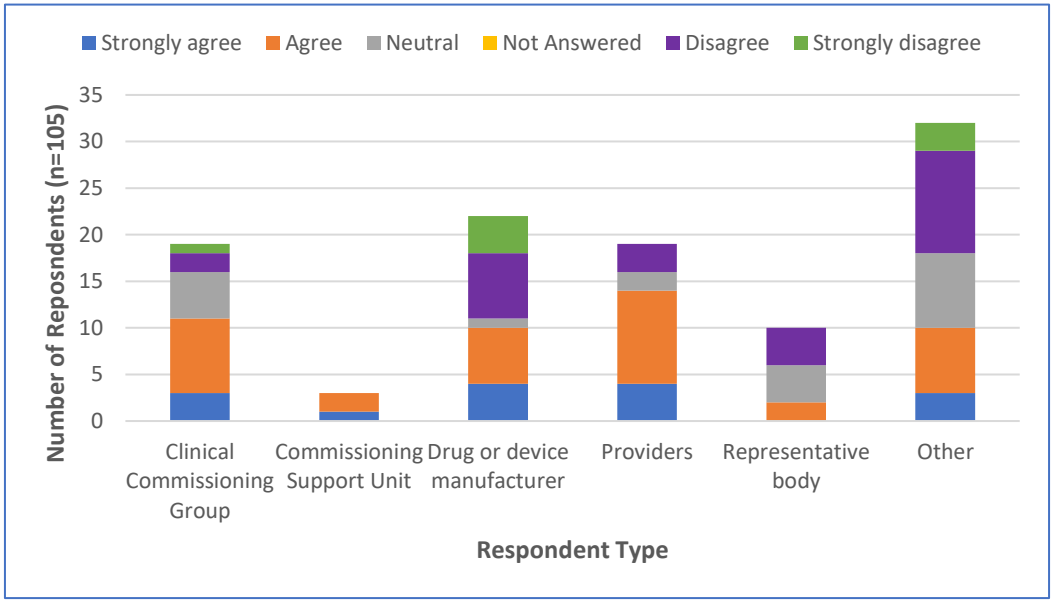
Question 2. To what extent do you agree that the MedTech funding mandate should cover digital innovations when the Digital Technologies Guidance becomes available?



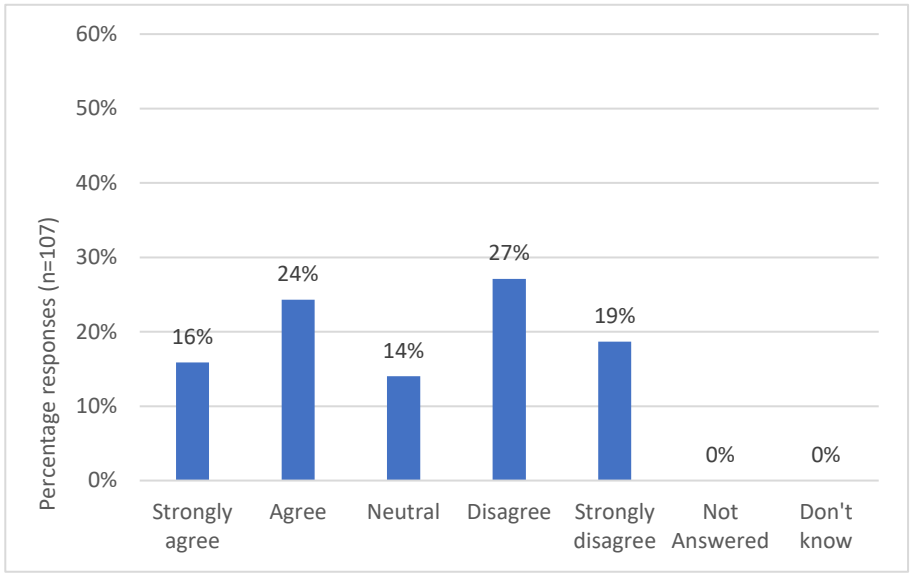


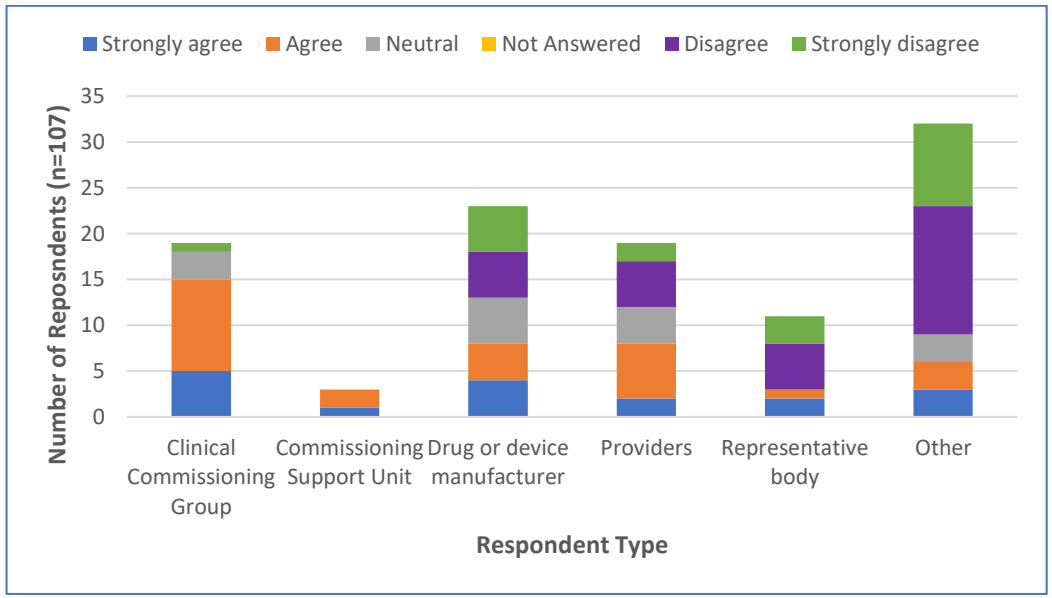
Question 3. To what extent do you agree that the MedTech funding mandate should only cover innovations that deliver material savings, i.e. over £1 million over five years for the population of England?



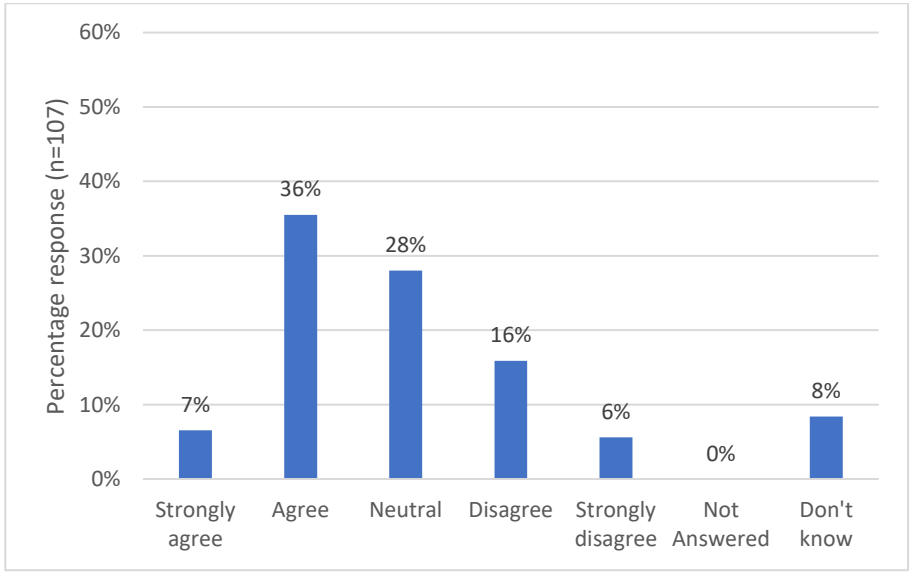


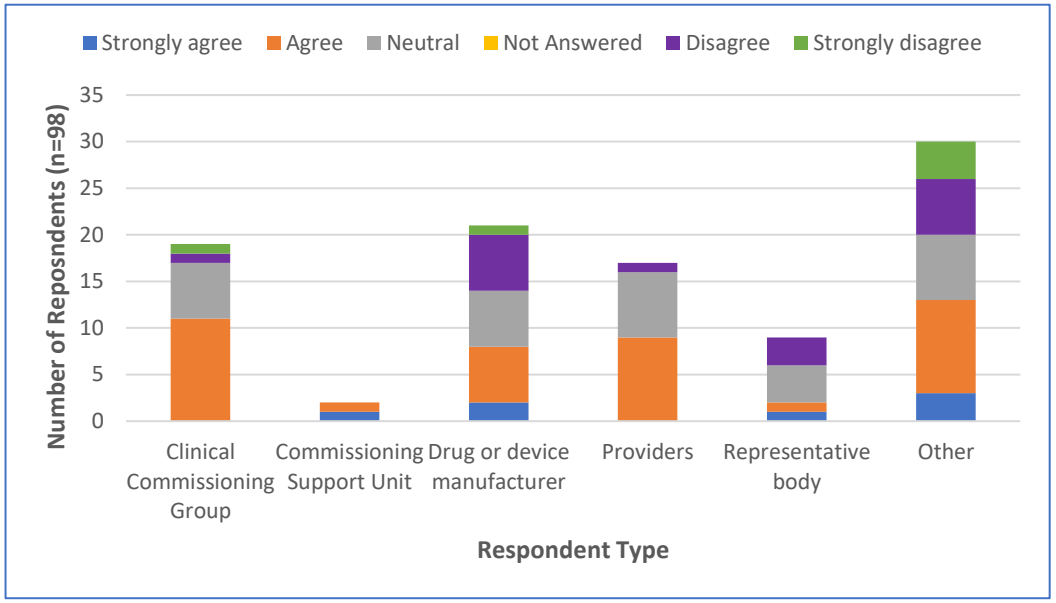
Question 4. To what extent do you agree that the MedTech funding mandate should only cover innovations that are likely to deliver net savings in the first 12 months based on NICE assessments?



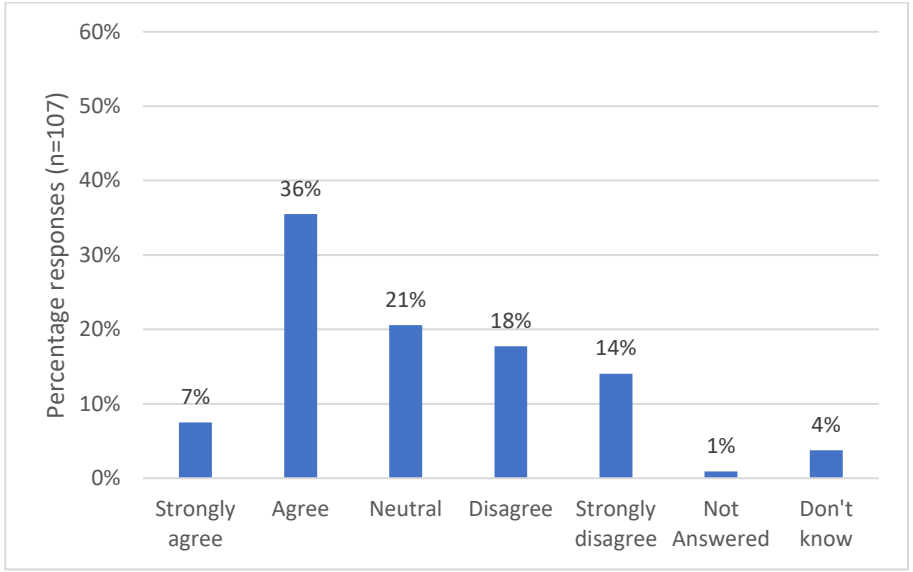


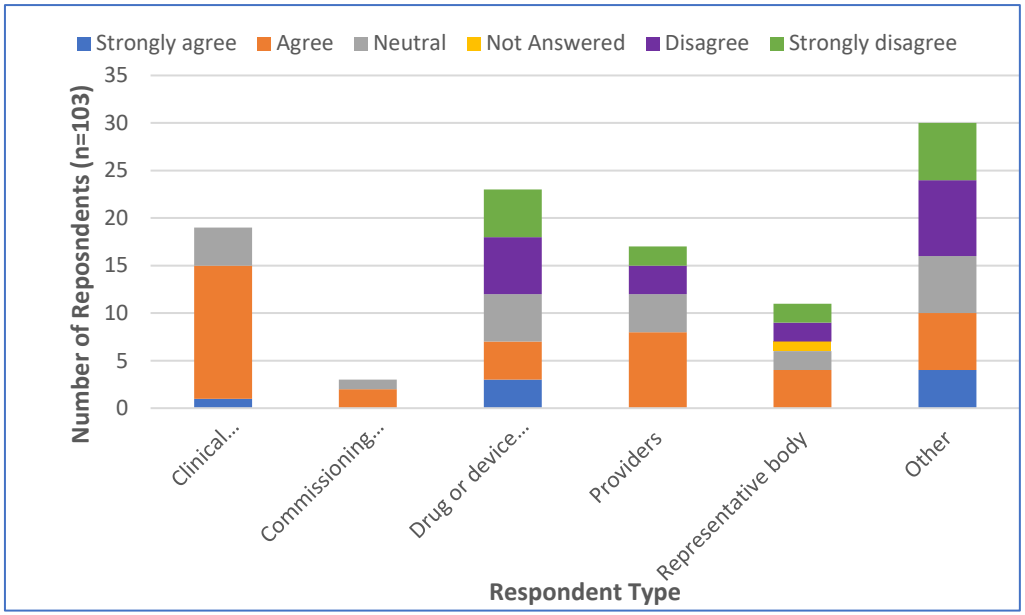
Question 5. To what extent do you agree that the budget impact of innovations covered by the MedTech funding mandate should not exceed £20 million, in any of the first 3 years?



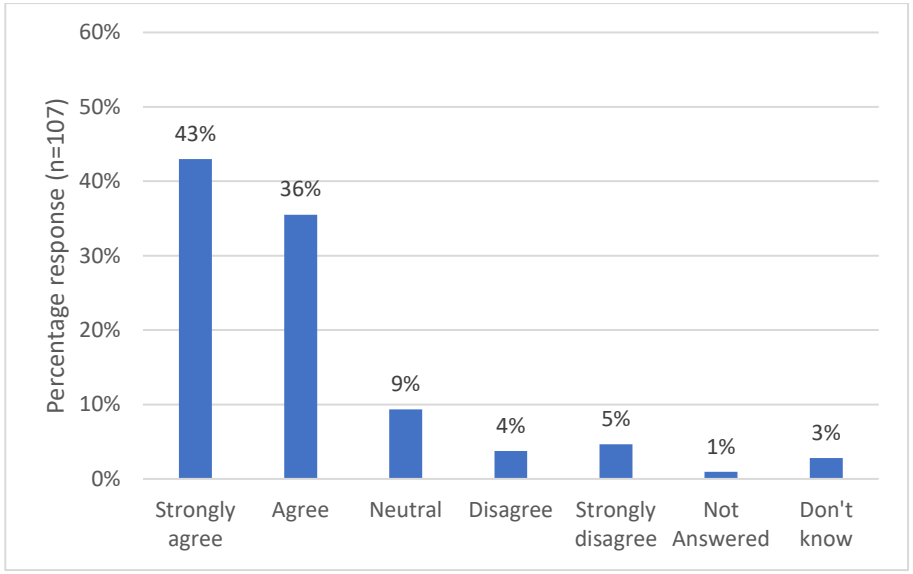


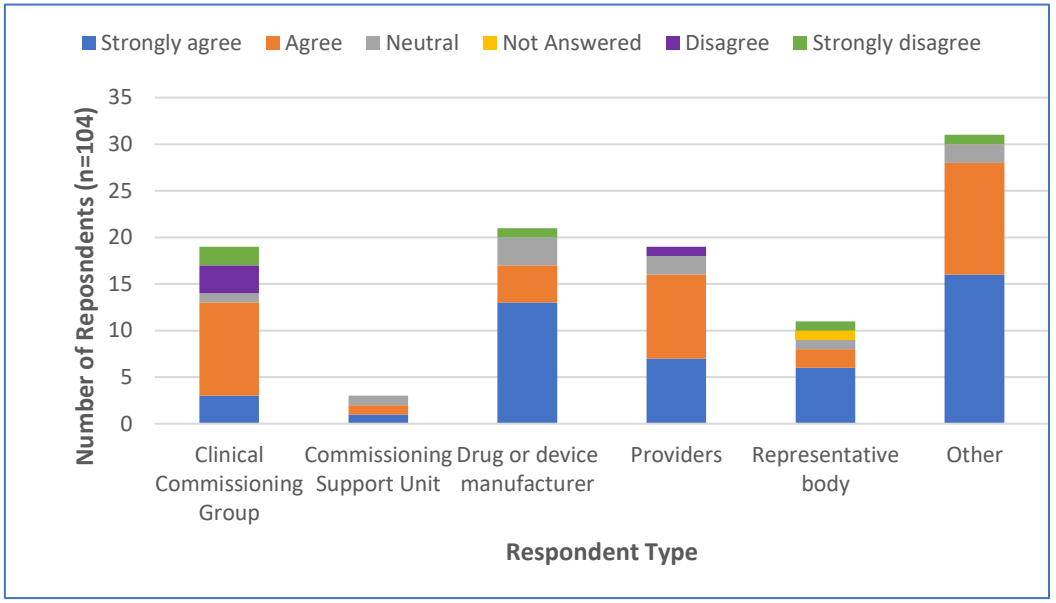
Question 6. To what extent do you agree with the proposal to limit the scope of the MedTech funding mandate to innovations previously supported by the ITT and with a published NICE guidance in 2020/21?



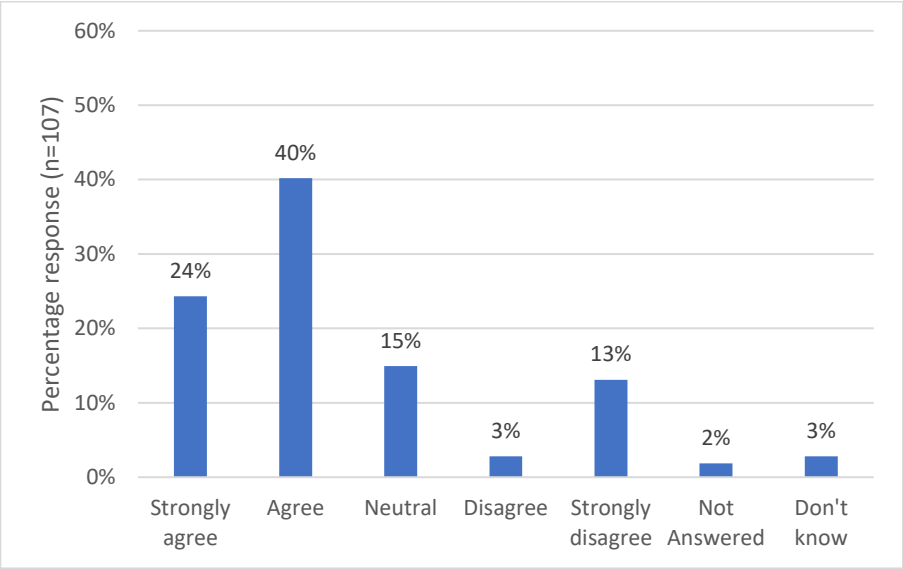


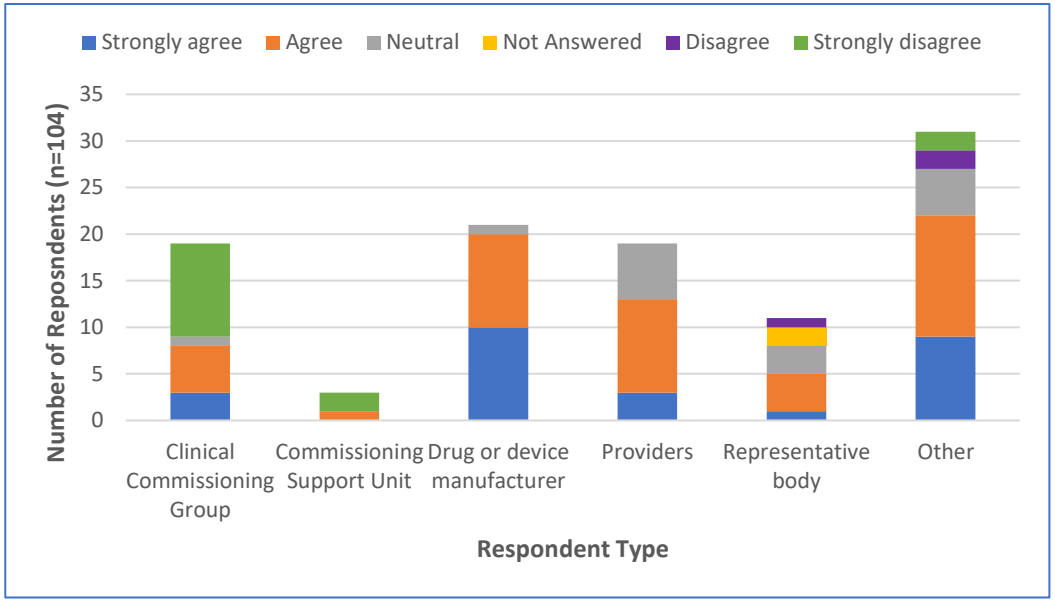
Question 7. To what extent do you agree that the savings calculations should include both 'cash releasing' and 'non-cash' releasing' savings?



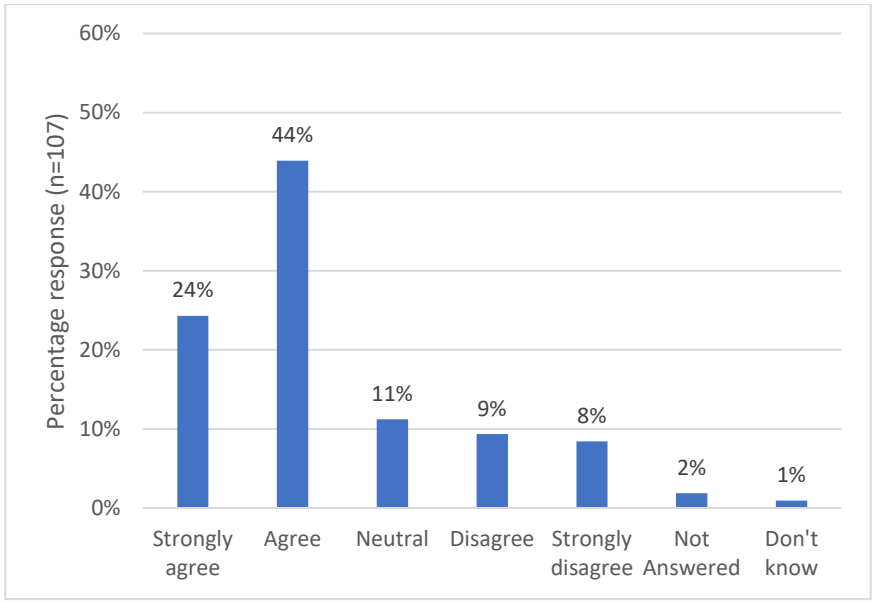


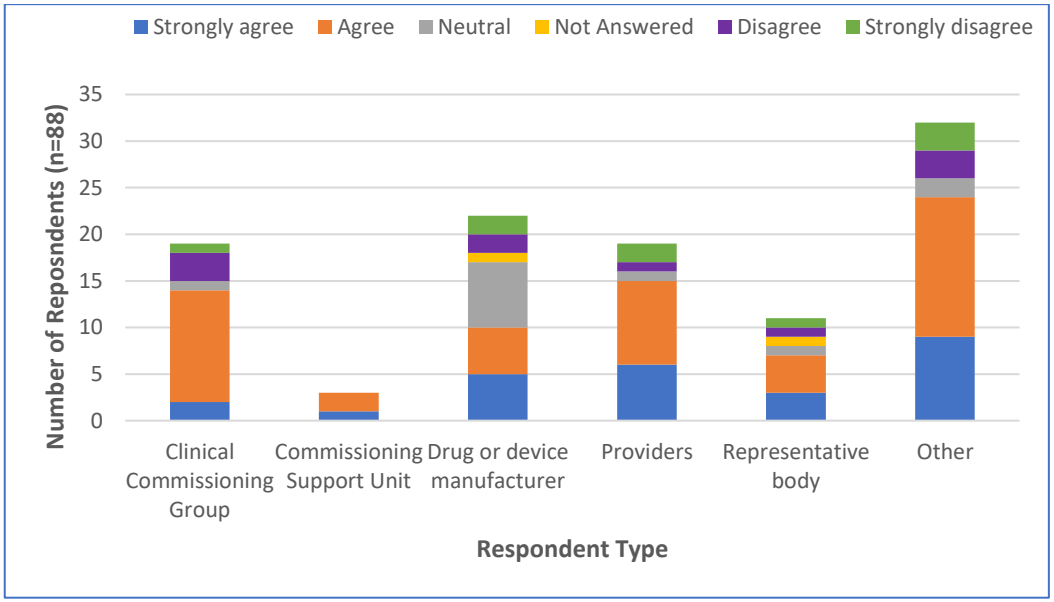
Question 8. To what extent do you agree with the proposal to use NHS England and NHS Improvement guidance and inclusion in the NHS Contract as the main mechanisms for implementing the MedTech funding mandate?



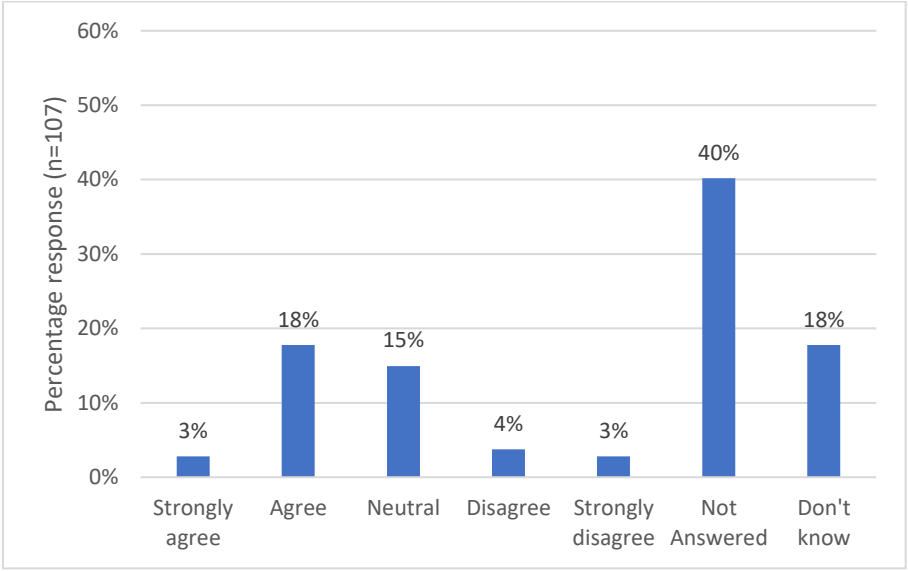


Question 9. To what extent do you agree with the proposal to pilot the MedTech funding mandate Policy with a limited number of products in the first year?

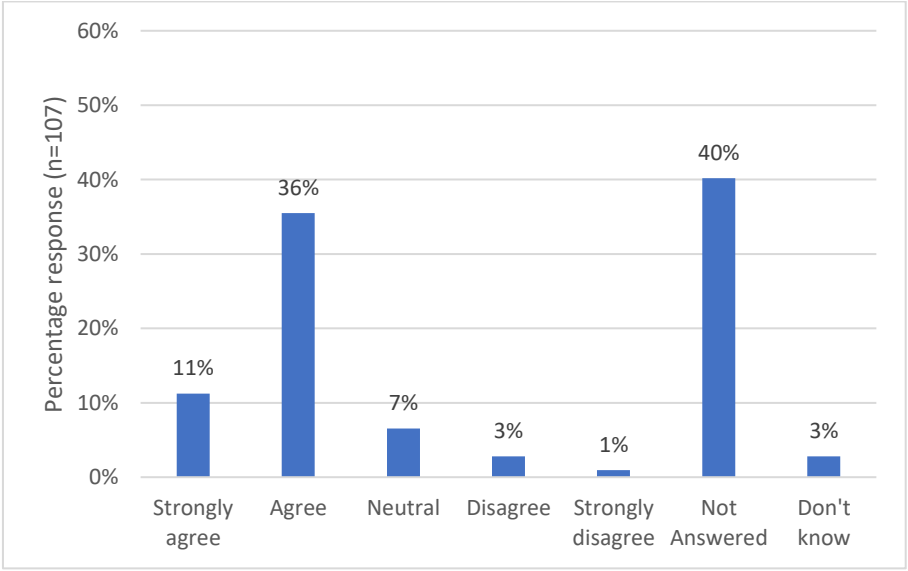




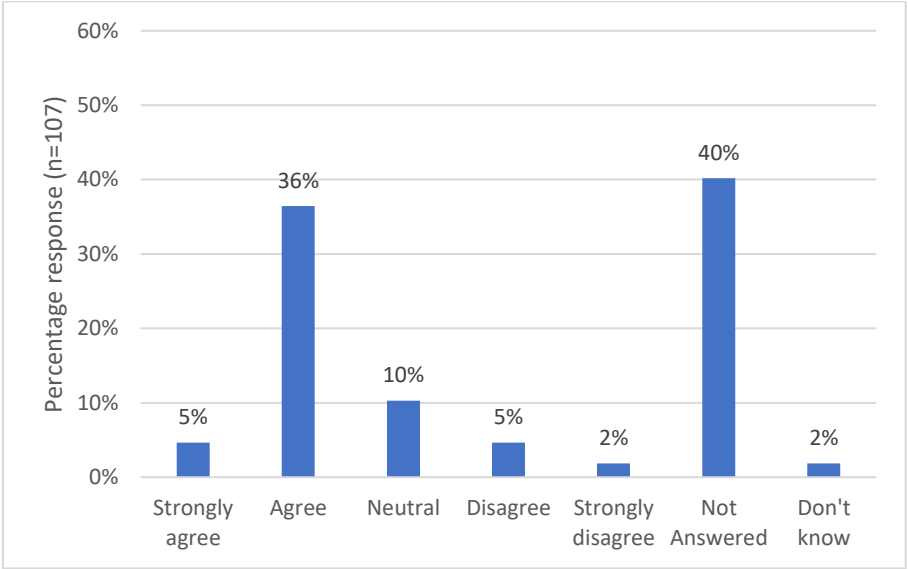
Question 10. To what extent do you agree with the proposed procurement and reimbursement arrangements for innovations that will be covered by the MedTech Funding Mandate Policy in 2020/21?



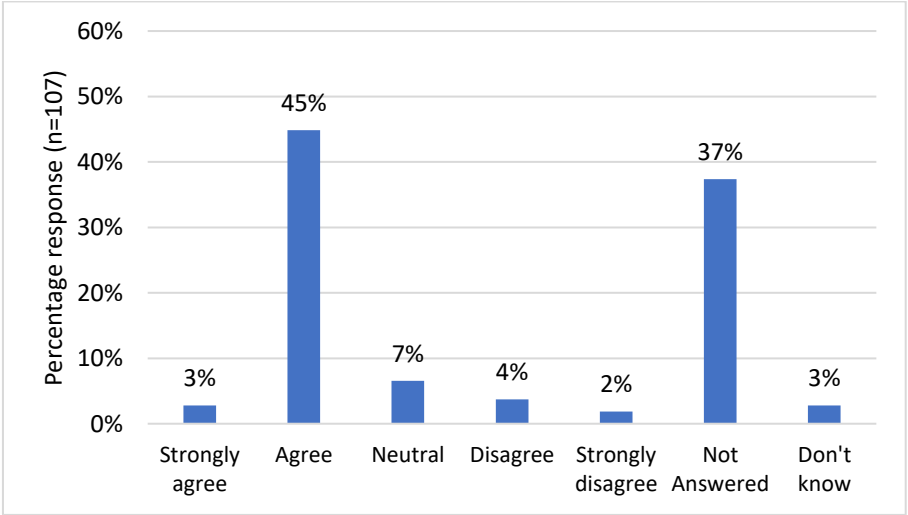
Question 11. To what extent do you agree with the implementation support which is proposed to be provided for innovations covered by the proposed MedTech Funding Mandate policy?



Question 12. To what extent do you agree with the proposed monitoring process?



Question 13. To what extent do you agree with the proposed evaluation process?



Appendix C: Contract and payment system plans

NHS England and NHS Improvement's proposals for the 2020/21 National Tariff Payment System consultation (20 December 2019 to 22 January 2020)

The consultation on the 2020/21 NTPS Payment System (specifically Section 8.5, on the Innovation and technology tariff/innovation and technology payment), feedback has also indicated support for our approach to ITT/ITP and MedTech Funding Mandate proposal. Of the 53 respondents who answered the specific question on this proposal, 68% supported or strongly supported our approach. The qualitative feedback also aligns with the MFM consultation feedback that a slower, more phased approach should be taken to transitioning from the Innovation and Technology Payment (ITP) Programme to the MedTech Funding Mandate.

NHS Standard Contract Consultation (19 December 2019 to 31 January 2020)

The proposal to include a requirement in the NHS Standard Contract for commissioners and providers to comply with their obligations under the MedTech Funding Mandate was strongly supported, with 92 of those responding on this issue in favour and only 15 against.

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