NHS England and NHS Improvement

Consultation on the proposals for the MedTech Funding Mandate Policy

November2019

NHS England and NHS Improvement MedTech Funding Mandate Policy

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Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

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1. Executive summary

The introduction of a MedTech[1] Funding Mandate Policy is a NHS Long Term Plan commitment to accelerate the uptake of selected NICE-approved cost-saving devices, diagnostic and digital innovations in the NHS.

Currently providers of NHS commissioned services ("providers") and NHS commissioners may not be aware of new devices, diagnostics and digital innovations that improve patient care and service efficiency. In addition, those that are aware of these innovations, may find they are not included on common procurement frameworks or do not have sustainable reimbursement mechanisms in place. As a result, patients' access to these innovations may be delayed and providers and NHS commissioners may not capture potential service efficiencies.

The MedTech Funding Mandate Policy aims to address these issues through: providing guidance for NHS commissioners and providers each year on which NICE-approved devices and diagnostics (and ultimately digital therapeutics) improve patient care and reduce costs in-year. The uptake of these innovations will be supported through including them on national procurement frameworks, proposing reimbursement mechanisms and providing small amounts of financial support to assist providers with implementation.

It is proposed is that the MedTech Funding Mandate Policy will create a requirement from NHS England and NHS Improvement to providers and NHS commissioners to comply with National Institute for Health and Care Excellence[2] (NICE) Medical Technologies Guidance (MTGs) and, when available, NICE Diagnostic Guidance (DGs) for innovations that meet the following proposed criteria:

i) are effective;
ii) deliver material savings to the NHS;
iii) are cost-saving in-year[3]; and
iv) are affordable to the NHS.

We propose to implement the MedTech Funding Mandate Policy ("the Policy") by producing guidance, updated annually, for providers and NHS commissioners, published on the Future NHS webpage, to include detailed information on the Policy, what is required of providers and NHS commissioners and a list of technologies covered. We propose that an obligation is

[1] For this consultation, "MedTech" refers to Medical Technologies: medical devices, diagnostics and digital products
[2] Details about the NICE Medical Technologies Evaluation Programme can be found here: https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-medical-technologies-evaluation-programme
[3] Deliver more savings than they cost within 12 months

placed on both NHS commissioners and providers in the NHS Standard Contract requiring them to comply with and observe recommendations made by guidance produced under the Policy. (There will be further consultation on the proposed wording to be included in the NHS Standard Contract in accordance with Standing Rules regulations.)

The MedTech Funding Mandate Policy builds on the Innovation Technology Payment[4] (ITP) programme, setting out future procurement and reimbursement arrangements for technologies that meet the proposed criteria (including products currently supported by the ITP).

We will also propose to support getting these technologies to patients faster by:

- **Reducing procurement barriers to adoption** – working with NHS Supply Chain so that products covered by the MedTech Funding Mandate Policy are available on the relevant procurement framework so that NHS trusts and Foundation Trusts will not need to run their own local or regional procurements.
- **Providing clarity on which type of organisation pays for these technologies** – we propose that when the primary financial benefit is realised by NHS commissioners, these technologies will go on a tariff excluded list and NHS commissioners will pay as a pass through payment. Conversely, where providers are the primary financial beneficiary, the technology will not go on the excluded list and providers will not receive an additional payment above the relevant tariff.

To reduce the financial risk for providers and NHS commissioners, and to ensure implementation is manageable in the first year (2020/21), we propose piloting the Policy with a limited number of products that both meet the proposed criteria and were previously supported by the ITP programme. This will cover products with published NICE MTGs or DGs as of 30th June 2019.The products we propose for inclusion in the MedTech Funding Mandate Policy for 2020/21 are:

- **Placental Growth Factor (PlGF) based testing to help rule out pre-eclampsia**[5]
    - NICE estimates this will enable over 36,000 pregnant women to be safely discharged home instead of being admitted to hospital for 36 hours.
- **SecurAcath for securing percutaneous catheters**[6]
    - NICE estimates this will support over 100,000 patients to have their catheters secured without them needing to be replaced at weekly dressing changes.

[4] Details of the ITP can be found here: https://www.england.nhs.uk/ourwork/innovation/innovation-and-technology-payment-itp-2019-20/
[5] https://www.nice.org.uk/guidance/dg23
[6] https://www.nice.org.uk/guidance/mtg34

- **HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography**[7]
    - NICE estimates this will enable clinicians to safely avoid unnecessary and invasive cardiac procedures in around 23,000 patients over the next 5 years

NICE estimate the financial benefit of implementing these three technologies will release £3.9m in the first year and £20m over five years. Further detail is provided in Annex 1.

This consultation outlines the important questions we are seeking input on for this Policy.

2. Introduction

In the NHS Long Term Plan, NHS England and NHS Improvement committed to introduce a MedTech Funding Mandate in April 2020 as part of the wider strategy to accelerate the uptake of selected NICE approved cost-saving MedTech products in the NHS.

This document is a consultation on the MedTech Funding Mandate Policy. It provides details on the proposed MedTech Funding Mandate Policy and invites views on different aspects of the Policy.

3. Background

We proposed introduce this Policy to get clinically effective, cost-saving innovations to patients faster. To achieve this, this policy aims to:

a. **give direction to the NHS on which MedTech innovations are effective, likely to give quick returns on investment;** and
b. **ensure we have a more sustainable approach to addressing financial barriers to adopting MedTech technologies in the NHS**

This Policy proposal builds on our previous innovation programmes; in 2017, the Innovation and Technology Tariff / Payment programme (ITT / ITP) was introduced by NHS England to address financial and procurement barriers to the adoption of devices, diagnostics and digital products, through centralised procurement of a selected number of products, making them available to NHS trusts and Foundation Trusts free of charge.

We are proposing to introduce the MedTech funding Mandate Policy from April 2020 to provide a more sustainable approach to procurement and reimbursement of NICE-approved cost-saving devices, diagnostics and digital products and to discontinue the Innovation and Technology Payment programme in its current form.

[7] https://www.nice.org.uk/guidance/mtg32

4. Consultation Details

4.1. What are we consulting on?

This consultation sets out the MedTech Funding Mandate Policy proposal. It gives an overview of the Policy intention, the criteria for selecting innovations covered by the MedTech Funding Mandate Policy, the mechanisms that will be used to implement the Policy, the implementation support that will be provided for innovations and the ways in which it is proposed that providers and NHS commissioners will be expected to demonstrate compliance with the Policy

4.2. Who is the target audience?

We have developed this consultation document for individuals and / or organisations that may be directly affected by the MedTech Funding Mandate Policy as well as those with particular interest in healthcare / health policy. Specifically, the target audience for this consultation includes: patients, providers of NHS commissioned services, NHS commissioners, policy makers, regulators, innovators, and arm's length bodies such as NICE.

Those providing feedback have an option to respond to the all consultation questions or to only provide responses to specific questions in the consultation document.

4.3. What is the duration of the consultation?

The consultation will run for 30 days, starting on 05.11.2019 and ending on 18.12.2019.

4.4. How to respond to this consultation?

You can submit your feedback to this consultation through the NHS England and NHS Improvement consultation site here:

https://www.engage.england.nhs.uk/consultation/medtech-funding-mandate

The deadline for submitting online responses is midnight on 18.12.2019.

Following the online consultation, we will host two engagement events:

- London on Monday 16th December 11am – 1pm; and
- Leeds on Wednesday 18th 10am – 12pm (noon)

Please contact NHS England and NHS Improvement's consultation team on england.innovation@nhs.net if you have any questions about this consultation, if you require

a paper copy of this consultation document or to register your interest in attending one of the engagement events[8].

4.5. How your responses will be used

Under the General Data Protection Regulation and the Data Protection Act 2018. NHS England and NHS Improvement will be data controllers for any personal data you provide as part of your response to the consultation. NHS England and NHS Improvement have statutory powers they will rely on to process this personal data which will enable them to make informed decisions about how they exercise their public functions. If you respond as a private individual, we will anonymise your response but we may publish your response in part or full unless you tell us not to. If you respond on behalf of an organisation, we will list your organisation's name and may publish your response in full unless you tell us not to. If you want any part of your response to stay confidential, you should explain why you believe the information you have given is confidential.

NHS England may need to disclose information under the laws covering access to information (usually the Freedom of Information Act 2000). If you ask us to keep part or all of your response confidential, we will treat this request seriously and try to respect it but we cannot guarantee that confidentiality can be maintained in all circumstances.

4.6. After the Consultation

We will consider all responses received during the consultation period before deciding on whether, and how, to progress the MedTech funding mandate policy. A summary of the responses will be published on the NHS England and NHS Improvement's website.

Should we proceed with this proposed Policy we will then publish the final Policy and guidance relating to it on the NHS England and NHS Improvement Website.

5. What is the MedTech Funding Mandate Policy?

5.1. What are the aims of the MedTech Funding Mandate Policy?

We are proposing to introduce this Policy to get clinically effective, cost-saving innovations to patients faster.

To achieve this, this policy aims to:

[8] Due to logistical and capacity constraints, we may not be able to accommodate every request to attend.

a. **give direction to the NHS on which MedTech innovations** are effective, likely to give quick returns on investment and recommended by NHS England and NHS Improvement, so that they can be made available to patients faster and more consistently; and

b. **ensure we have a more sustainable approach to addressing financial barriers to adopting MedTech technologies in the NHS** by clearly setting out how the selected technologies should be funded and procured.

The proposal for this Policy is that the MedTech Funding Mandate will be a requirement from NHS England and NHS Improvement to providers and NHS commissioners to comply with NICE Medical Technologies Guidance (MTGs) and NICE Diagnostic Guidance (DGs) for innovations that meet the proposed criteria for the MedTech Funding Mandate Policy.

5.2. What are the proposed criteria for the MedTech Funding Mandate Policy?

Working in collaboration with key stakeholders who include: NHS England and NHS Improvement's Strategic Finance, NICE, NHS Clinical Commissioners, NHS Providers, NHS Supply Chain, The Office for Life Sciences, Shelford Group and industry groups, we have developed the proposed criteria for the MedTech Funding Mandate, to include medical devices, diagnostics and digital therapeutics that:

a. **are effective:** demonstrated through a positive NICE Medical Technologies Guidance (MTGs), NICE Diagnostic Guidance (DGs) or NICE Digital Guidance (DiGs)(when available);
b. **deliver material savings to the NHS:** the benefits of the innovation are over £1 million over five years for the population of England;
c. **are cost-saving in-year[9]:** NICE modelling demonstrates a net saving in the first 12 months of implementing the technology; and
d. **are affordable to the NHS:** the budget impact does not exceed £20million, in any of the first 3 years[10].

[9] We propose using a NICE cost consequence analysis for this as it will give us the savings broken down by year; currently this type of analysis is part of MTGs and DGs (through the Medical Technology Appraisal Programme) and is why we are proposing the policy should only apply to technologies that have a positive recommendation through these two routes and that cost consequence analysis should be incorporated into the NICE Diagnostic Guidance once available.

[10] Should this budget impact be exceeded, NHS England and NHS Improvement reserves the right to not include the product in the MedTech Funding Mandate and / or to engage in further commercial negotiations with the relevant party/ies

NICE provides recommendations, in the form of guidance[11], on the use of medicines, devices, diagnostics and other interventions, providing independent advice to the NHS on the efficacy, costs and benefits of these innovations. We considered inclusion of the following types of NICE guidance:

- **Technology Appraisal (TA) or Highly Specialised Technologies Evaluation (HST)** – these provide recommendations on the use of new and existing health technologies (out of scope for this policy as these are already covered by a funding direction and are referenced in NHS constitution).
- **Clinical Guidelines (CGs)** – these provide guidance on the appropriate treatment and care of people with specific diseases and conditions (out of scope for this policy as these do not include the cost consequence analysis required for the proposed criteria)
- **Interventional Procedures Guidance (IPGs)** - these provide advice on the safety and the efficacy of new interventional procedures. These may be procedures approved for normal use, procedures which should not be used and those which may be used with certain safeguards (out of scope for this policy as these do not include the cost consequence analysis required for the proposed criteria)
- **Medical Technologies Guidance (MTGs)** – these are designed to help the NHS adopt efficient and cost- effective medical devices and diagnostics more rapidly and consistently. The types of products which might be included are medical devices that deliver treatment such as those implanted during surgical procedures, technologies that give greater independence to patients, and diagnostic devices or tests used to detect or monitor medical conditions (MTGs are in scope for this policy)
- **Diagnostic Guidance (DGs)** – (DGs that come through the MTEP programme are in scope for this policy) these are designed to help people in the NHS make efficient, cost-effective and consistent decisions about adopting new diagnostics for:
    - ruling in or out a specific disease;
    - general examination looking for clues to the cause of the symptoms;
    - staging, or additional testing to assess how advanced or severe the disease is;
    - monitoring a patient over time to determine changes in their condition;
    - screening tests to look for conditions in patients without signs or symptoms of the specific condition.
- **NICE Digital Guidance (DiGs)** – NICE are piloting the assessment of four digital technologies and will use the learning from this pilot to inform the development of their

[11] Full details on NICE's scope and processes are available here: https://www.nice.org.uk/

assessment of digital health technologies in conjunction with the consultation on the evidence standards framework for digital health technologies[12].

NHS commissioners are legally required to comply with NICE guidance in Health Technology Appraisals (HTA) and Highly Specialised Technologies (HST). However, other types of NICE guidance (e.g. Medical Technologies and Diagnostic Guidance) are not subject to a mandatory funding requirement. Additionally, Service Condition 2.1.6 of the NHS Standard Contract requires providers to comply, where applicable, with recommendations contained in HTAs and have regard to other guidance issued by NICE from time to time.

Consultation Questions

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? **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)**

2. To what extent do you agree that the proposed MedTech Funding Mandate Policy should cover digital innovations when the Digital Technologies Guidance becomes available? **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)**

Please feel free to add a free text reason for each choice

The proposed scope of the MedTech Funding Mandate Policy is limited to NICE Medical Technologies Guidance (MTGs), Diagnostic Guidance (DGs) and, when available, NICE Digital Guidance, because other types of NICE guidance do not include the cost consequence analysis which enables determination of whether an innovation is likely to deliver in-year cost savings.

We recognise that cost savings in terms of financial benefits, there are both:

- **'Cash releasing'** - Resulting in 'cash in the bank' through avoided spend (e.g. reduced cost per test); or
- **'Non cash releasing'** - Benefits that can be monetised but don't result in 'cash in the bank (e.g. value in £ of hours dedicated to front line duties)

What other options did we consider?

Many NHS cost savings programmes focus primarily on 'cash releasing' savings whereas the analyses NICE use for their MTGs and DGs includes both these types of financial

[12] This consultation can be found here: https://www.nice.org.uk/news/article/evidence-standards-framework-for-digital-health-technologies

benefits. Our proposal is that we continue to look at both cash releasing and non cash releasing savings to provide a more holistic view of their impact.

Consultation Questions
3. To what extent do you agree that the proposed MedTech Funding Mandate Policy should only cover innovations that deliver material savings i.e. over £1 million over five years for the population of England? **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)** 4. To what extent do you agree that the proposed MedTech Funding Mandate Policy should only cover innovations that are likely to deliver net savings in the first 12 months based on NICE assessments? **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)** 5. To what extent do you agree that the budget impact of innovations covered by the proposed MedTech Funding Mandate Policy should not exceed £20million, in any of the first 3 years? **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)** 6. To what extent do you agree with the proposal to limit the scope of the proposed MedTech Funding Mandate Policy to innovations previously supported by the ITT and with a published NICE guidance in 2020/21? **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)** 7. To what extent do you agree that the proposed savings calculations should include **both** 'cash releasing' and 'non cash releasing' savings? **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)** Please feel free to add a free text reason for each choice

5.3. What mechanisms will be used to implement the proposed MedTech Funding Mandate Policy?

We propose to implement the MedTech Funding Mandate Policy by producing guidance for providers and NHS commissioners. We propose to include in the NHS Standard Contract for 2020/21 an obligation on NHS commissioners and providers to comply with their respective obligations under, and with recommendations made by that guidance (There will be further consultation on the proposed wording to be included in the NHS Standard Contract in accordance with Standing Rules regulations.

The proposed MedTech Funding Mandate Policy guidance will provide detailed information on the policy and specify the innovations that it is proposed to cover each year. This guidance will also be referenced on the FutureNHS webpage so NHS organisations can take this into account when developing their operational plans. The guidance may also be referenced in the relevant National Tariff Payment System documents and NHS Standard Contract, both of which will be subject to their consultations.

The proposal is for the Med Tech Funding Mandate Policy to apply from 1st April to 31st March each financial year.

What other options did we consider?

We considered making changes to the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 as part of the package of measures to implement the MedTech Funding Mandate Policy, but there was insufficient Parliamentary time available to ensure those changes could be made within the required timetable and consequently this option is not viable.

Consultation Questions
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? **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)** Please feel free to add a free text reason for each choice 9. Are there other implementation mechanisms that may be more effective that we could consider for this policy? **(Free text)**

5.4. What is the proposed process for selecting innovations covered by the proposed MedTech Funding Mandate Policy?

We propose setting up a panel that will review all NICE guidance published up to the 30th June each year and select innovations based on the criteria outlined above, that will be covered by the MedTech Funding Mandate Policy for the following year. This proposed process will also include a review of products already covered by the mandate to determine if there are any products that should be removed e.g. where there have been significant updates to the innovation that necessitate a review of NICE guidance. The selection process for technologies covered by the Policy is illustrated in Figure 1 (with a larger version included in Annex 1.

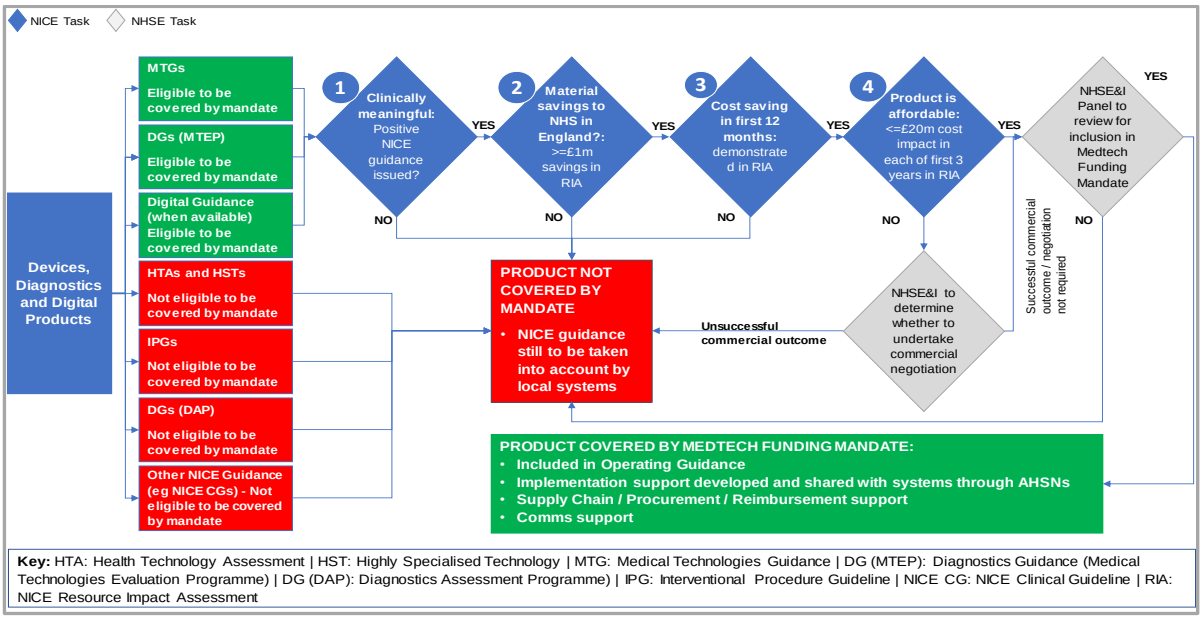


Figure 1: Proposed MedTech Funding Mandate Process

5.5. Which innovations will be covered by the proposed MedTech Funding Mandate Policy in 2020/21?

In order to identify the proposed eligible products we reviewed NICE MTGs and DGs up to 30th June 2019, which included 74 innovations and the 14 innovations previously included in the Innovation and Technology Tariff (ITT) and Innovation and Technology Payment (ITP) programmes.

We considered innovations based on the proposed criteria in section 5.2 above which led to 7 innovations meeting the proposed Policy criteria. Figure 2 outlines at which point other technologies did not meet the proposed MedTech Funding Mandate Policy criteria.

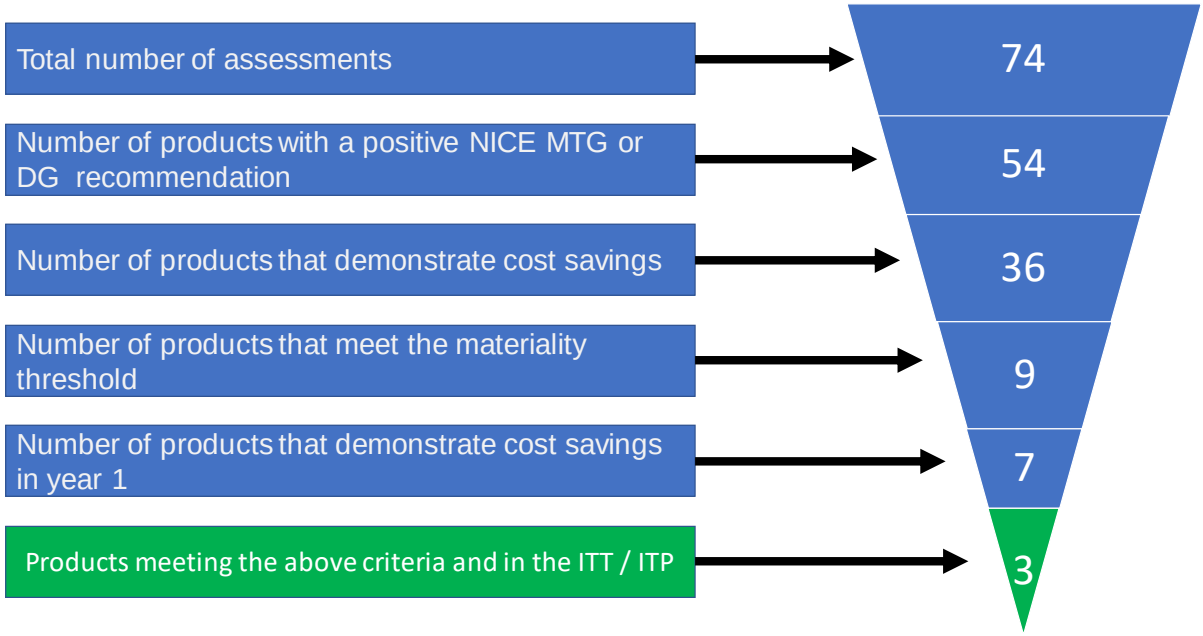


Figure 2: Review of NICE MTG and DG assessments - funnel diagram

Given the uncertainty over the implementation burden for providers and NHS commissioners, and to reduce the financial risk in translating nationally developed NICE assessments into local scenarios, not all of which it would be feasible to model, we propose piloting this policy with the handful of products that met the mandate criteria AND were ITP products. Of the 7 innovations that met the criteria, 3 are covered by the ITP and are the products that we propose being covered by the proposed MedTech Funding Mandate Policy for the first year. The other 4 products which met the proposed criteria but were not ITP products would be considered for inclusion in the proposed MedTech Funding Mandate Policy from April 2021.

During the pilot period we will gather feedback on the implementation model on providers and NHS commissioners and capture data on how the modelled clinical outcomes and savings are being achieved as well looking at what implementation support and models are most effective. We will use these data to refine and the Policy for 2021/22.

5.5.1. Placental Growth Factor (PlGF) based testing to help rule out pre-eclampsia

Placental growth factor (PlGF)based tests are intended to be used with clinical judgement and other diagnostic tests, to help diagnose suspected pre-eclampsia. This assessment focuses on diagnosing preeclampsia in the second and third trimesters of pregnancy. Using PlGF based tests in addition to standard clinical assessment could result in a faster and more accurate diagnosis of preeclampsia, and better risk assessment for adverse outcomes in women with suspected preeclampsia. It could also allow women in whom preeclampsia

has been ruled out with a PlGF based test to return to community care instead of being admitted to hospital for observation.

Further detail on this technology is provided on the NICE website[13].

5.5.2. SecurAcath for securing percutaneous catheters

SecurAcath (Interrad Medical) is a single-use device to secure percutaneous catheters in position on the skin.

The claimed benefits of SecurAcath are:

- no interruptions or delays in therapy because of improved catheter securement
- fewer repeat procedures by improving vessel preservation and reducing reinsertions
- fewer catheter complications (dislodgements, migration, thrombosis and infection)
- a decrease in catheter replacement costs
- a reduction in overall treatment costs because of fewer delays and complications.

Further detail on this technology is provided on the NICE website[14].

5.5.3. HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography

HeartFlow FFRCT (developed by HeartFlow) is coronary physiology simulation software used for the qualitative and quantitative analysis of previously acquired computerised tomography DICOM data. The software provides a non-invasive method of estimating fractional flow reserve (FFR) using standard coronary CT angiography (CCTA) image data. FFR is the ratio between the maximum blood flow in a narrowed artery and the maximum blood flow in a normal artery. FFR is currently measured invasively using a pressure wire placed across a narrowed artery.

The claimed benefits of HeartFlow FFRCT are:

- Analysis is done using standard CCTA scans, without the need for additional imaging, radiation or medication.
- It provides the same accuracy in excluding coronary artery disease as CCTA, and characterises the coronary arteries from both functional and anatomical perspectives, differentiating between ischaemic and non-ischaemic vessels in a way that CCTA cannot.

[13] https://www.nice.org.uk/guidance/dg23
[14] https://www.nice.org.uk/guidance/mtg34/chapter/2-The-technology

- It allows physicians to evaluate anatomic coronary artery disease and accurately determine which coronary lesions are responsible for myocardial ischaemia, avoiding unnecessary invasive diagnostic or therapeutic procedures and related complications.
- It reduces the need for revascularisation in patients after identifying anatomic stenosis by invasive coronary angiography (ICA) alone, by more accurately identifying if those stenoses are ischaemic.
- It improves the diagnostic accuracy for coronary artery disease compared with CCTA alone against the gold standard of invasive FFR, and provides both functional and anatomic assessment of coronary arteries.
- It has better diagnostic performance than CCTA alone, or other non-invasive or invasive tests (such as nuclear myocardial perfusion, magnetic resonance perfusion, stress echocardiography, exercise treadmill testing, invasive angiography or intravascular ultrasound) for detecting and excluding coronary artery lesions that cause ischaemia.
- It reduces costs arising from inconclusive or inaccurate diagnostic tests.
- It avoids staff and procedure costs for unnecessary ICAs.
- It avoids staff and procedure costs for unnecessary interventions (such as angioplasty).
- It provides a more effective use of high-cost invasive procedure suites, providing the opportunity to reduce waiting times for these facilities and increase patient turnaround.

Further detail on this technology is provided on the NICE website [15].

Consultation Questions
10. 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? **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)** Please give reasons for your choice

5.6. Proposed reimbursement approach for innovations that will be covered by the proposed MedTech Funding Mandate Policy in 2020/21

The proposed reimbursement arrangements for technologies will vary depending on the type of technology, anticipated financial impact and distribution of costs and benefit. As a general rule, we propose that providers to fund the innovation where the primary financial benefit

[15] https://www.nice.org.uk/guidance/mtg32/chapter/2-The-technology

accrues to providers and likewise, NHS commissioners to fund the innovation where the primary financial benefit accrues to NHS commissioners.

Where feasible, we propose to make adjustments to national tariff prices to account for the additional costs of the technologies.

We also propose to introduce an "Innovations and Technologies List" for new MedTech products that will be excluded from existing national tariff prices to inform local payment discussions and/or agreements. We propose to apply this list to technologies where the financial benefit accrues to NHS commissioners and that list will also include technologies with positive NICE MTGs, DGs or with available Digital Guidance that do not meet the proposed MedTech Funding Mandate Policy criteria.

5.7. Proposed procurement and reimbursement arrangements for innovations that will be covered by the MedTech Funding Mandate Policy in 2020/21

5.7.1. PlGF

Reimbursement

We propose that PlGF is not added to the innovation exclusion list as the primary financial benefit will be to providers.

Procurement

We proposed that NHS Supply Chain should add this technology to the relevant procurement framework and make this information available to NHS Trusts and Foundation Trusts. This would mean that NHS Trusts and Foundation Trusts would have the option of procuring through the relevant NHS Supply Chain framework rather than undertaking their own procurement process.

5.7.2. SecurAcath

Reimbursement

We propose that SecurAcath is not added to the innovation exclusion list as the primary financial benefit will be to providers.

Procurement

We proposed that NHS Supply Chain should add this technology to the relevant procurement framework and make this information available to NHS Trusts and Foundation Trusts. This would mean that NHS Trusts and Foundation Trusts would have the option of

procuring through the relevant NHS Supply Chain framework rather than undertaking their own procurement process.

5.7.3. HeartFlow

Reimbursement

We propose adding this to the "Innovations and Technologies List", as a new category of exclusions from the National Tariff meaning that it will be treated as a 'pass through payment' (though this will likely be a generic term such as "Functional coronary CT angiography" rather than as "HeartFlow")

Procurement

We propose that HeartFlow implementation should be supported through:

- NHS Supply Chain to look to add this technology to the relevant procurement framework and make this information available to NHS Trusts and Foundation Trusts
- Developing a 'nominated supply cost' (our preferred option) that would be the maximum a commissioner would reimburse a provider for the use of this technology. Using this we could require NHS commissioners to specify to their provider Trusts and FTs, a procurement framework through which it should be procured. The provisions of the existing Service Condition 39 of the NHS Standard Contract may need to be amended to accommodate this (proposed changes to the NHS Standard Contract will be the subject of separate consultation)
- Updating the local pricing rule 5 in the National Tariff Payment System (also subject to a separate consultation) to clarify that reference prices or 'nominated supply costs' may be set for medical technologies as well as drugs, and that the local price agreed should reflect these reference prices or nominated supply costs

Other options explored:

We explored developing a 'reference cost' (an alternative option to the 'nominated supply cost' approach) for "Functional coronary CT angiography" that would enable us to financially incentivise providers to uptake the technology by setting a price higher the cost of the technology, however we do not propose using this option as we believe this guidance will be more effective at increasing uptake of these innovations where we can remove procurement barriers, such as by encouraging NHS trusts and Foundation Trusts to use NHS Supply Chain rather than developing an approach that would lead to multiple organisations undertaking very similar procurement activities.

Consultation Questions
11. 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 **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)** Please feel free to add a free text reason for each choice 12. Is there another implementation mechanism we should consider using? **(free text)** **13.** Should we use the 'reference cost' approach or the 'nominated supply cost' approach where this is applicable? **(free text)**

5.8. What implementation support is proposed to be provided for innovations covered by the proposed MedTech Funding Mandate Policy?

NICE develops tools to help provider organisations implement NICE guidance including:

- costing statements and resource impact reports explaining the resource impact guidance
- resource impact templates to help local areas assess the financial impact of the guidance

We propose to develop a bespoke spread plan for each with implementation supported through the Academic Health Science Networks (AHSNs) for each product covered by the MedTech Funding Mandate Policy to help increase uptake.

In addition, we could also use the Pathway Transformation Fund which to helps NHS organisations integrate innovations into everyday practices. The Pathway Transformation Fund could help providers overcome practical obstacles to deploying these products, such as: training staff on how to use new equipment; pathway redesign and/or business support expertise; providing specialist nurses/clinical staff needed to implement a new part of the procedure; or covering double running costs. Further information on the Pathway Transformation Fund can be found on the gov.uk website[16].

Consultation Questions
14. To what extent do you agree with the implementation support which is proposed be provided for innovations covered by the proposed MedTech Funding Mandate Policy **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)**

[16] https://www.gov.uk/government/news/86-million-funding-announced-for-new-medicine-and-technology

15. Is there other implementation support we or NICE could consider providing? **(free text)**

5.9. How will providers and commissioners be expected to demonstrate compliance with the proposed MedTech funding mandate?

All providers of NHS services and NHS commissioners will be expected to comply with the MedTech Funding Mandate Guidance except when:

- The NICE recommendations are not relevant to the organisation (e.g. a provider does not provide services to the specific patient cohort the technology supports); or
- Local circumstances mean there are material differences to the NICE Resource Impact Assessment technology meaning the technology is unlikely to deliver cost savings (e.g. if there is a local tariff arrangement that makes a material difference to the savings); or
- The technology requires significant upfront capital investment that does not align with the organisations' clinical or financial plans

Providers and NHS commissioners may evidence compliance with MedTech Funding Policy guidance in one or more of the following ways:

- NHS commissioners could publish policy statements, service level agreements and/or contracts which demonstrate funding is in place and that they require innovations covered by the MedTech funding mandate to be available for use, in consultation with the patient, and when recommended by NICE as part of their treatment pathway
- Providers could publish their policies and clinical care pathways to demonstrate that innovations covered by the MedTech funding mandate are available for use, in consultation with the patient, and when recommended as part of their treatment.
- Organisations could publish audit data and patient surveys to demonstrate the use of innovations covered by the MedTech funding mandate. This would include evidence that patients believe treatment options were discussed with them and their preferences taken into account

The process for determining whether an organisation needs to comply with the mandate is outlined in Figure 3 (a larger version is also outlined in Annex 4):

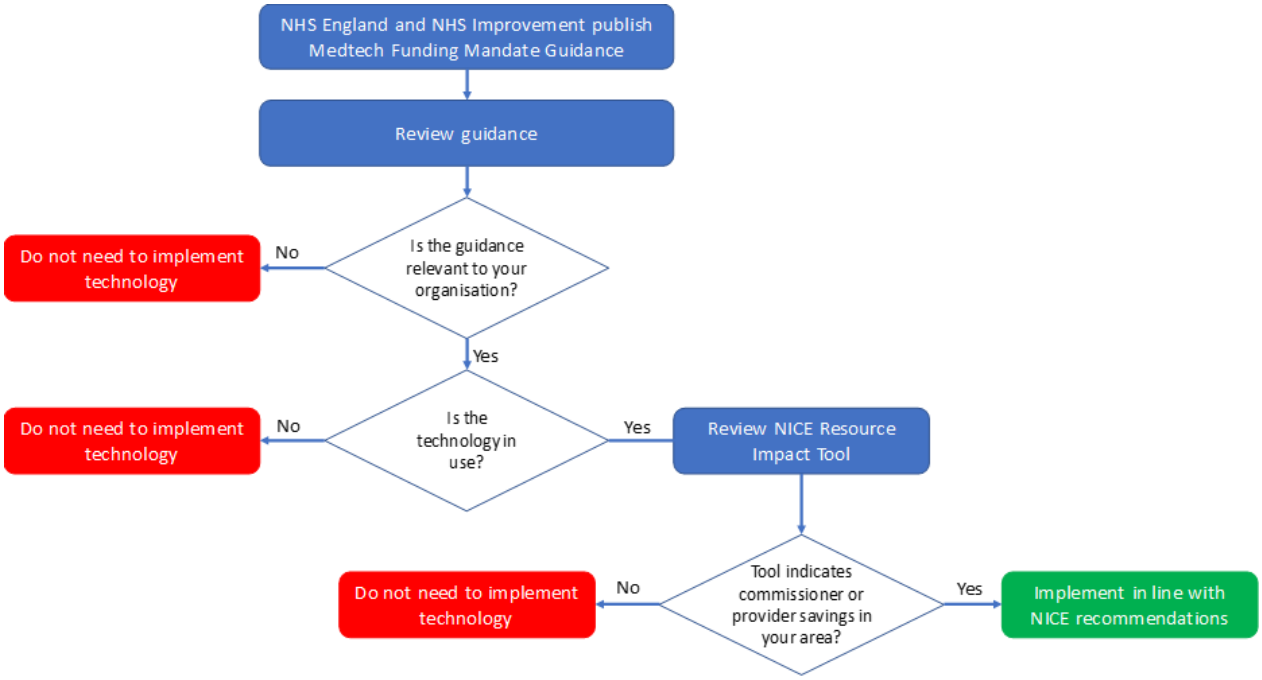


Figure 3: Flow chart for determining whether an NHS organisation needs to comply with the MedTech Funding Mandate Policy

Consultation Questions
16. Are there other ways in which providers and commissioners of NHS services could evidence compliance? **(free text)**

5.10. What financial impact is the implementation of these technologies likely to have?

For the three technologies we propose being included in the MedTech Funding Mandate Policy for 2020/21, the resource impact assessment estimates that:

- Without implementation these technologies the cost of care would be around £103.5m over five years; and
- By implementing them the cost of care would reduce to £82.9m over five years

The proposed implementation would therefore be **a net saving to the health system of over £20m over five years**.

Table 1 shows the breakdown by product of the resource impact assessments.

Product	Guidance	Estimated costs of current practice	Estimated costs of future practice (Y 5)	Resource Impact (Y5)
SecurAcath	MTG34	£7,041,642	£2,799,535	£4,242,107
PlGF	DG23	£25,192,992	£17,926,527	£7,266,465
HeartFlow	MTG32	£71,298,007	£62,113,559	£9,156,400
Total (for 3 products)		**£103,532,641**	**£82,839,621**	**£20,664,971**

Table 1: Estimated cumulative resource impact of technologies covered by the MedTech Funding Mandate Policy by Y5 (based on NICE assumptions)

6. Proposed Monitoring and Evaluation

6.1. Monitoring

For 2020/21 we propose to monitor the uptake of these products through sales data provided by the manufacturers. For future years we propose to consider inclusion of the uptake of these products in the NHS England Innovation Scorecard[17], hosted by NICE to provide transparency about NHS organisation's uptake of medical technologies covered by the MedTech Funding Mandate Policy.

We also propose to develop outcome measures to determine whether the technologies having the expected clinical impact.

- For HeartFlow we propose that this outcome measure would be the reduction in in invasive diagnostic or therapeutic procedures and related complications
- For PlGF we propose that this outcome measure would be reduction in early interventions (deliveries) due to a suspicion of pre-eclampsia alone (to see whether this reduces)
- For SecurAcath we have not yet identified routinely collected data that would support a proposed outcome measure without placing a disproportionate burden on providers and NHS commissioners

In addition, we will explore whether NHS organisational performance could be monitored through the NHS Oversight Framework and Care Quality Commission (CQC) Assessment Framework.

Consultation Questions
17. To what extent do you agree with the proposed monitoring process **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)** Please feel free to add a free text reason for each choice 18. Are there other monitoring approaches we should consider? **(Free text)**

6.2. Evaluation

We propose to evaluate the impact of the Policy on patients, providers and manufacturers during 2020/21 to determine what could be improved for subsequent years. This proposed evaluation will be included in the selection of future devices, diagnostics and digital products that will be covered by the Policy We propose to specifically look to see:

[17] The NHS England Innovation Scorecard can be found here: https://www.england.nhs.uk/ourwork/innovation/innovation-scorecard/

- Whether the clinical and financial benefits detailed in the NICE assessments are being delivered in the real world settings;
- The implementation impact on providers and NHS commissioners; and
- The impact of the implementation support and support materials and what could further support the adoption and spread of these innovative technologies.

Consultation Questions
19. To what extent do you agree with the proposed evaluation process **(strongly agree, agree, neutral, disagree, strongly disagree, don't know)** Please feel free to add a free text reason for each choice 20. Are there other evaluation approaches we should consider? **(Free text)**

7. Equality and health inequality considerations

With regard to both the equality and health inequalities considerations, NHS England and NHS Improvement view the impact of this proposal as positive. This is because it is anticipated that it increase the uptake of proven, affordable innovations . This may remove or minimise disadvantages suffered by people due to equality and health inequalities issues when accessing Medtech.

The Equality and Health Inequalities Impact Assessment can be requested via england.innovation@nhs.net .

Thank you for participating in this consultation

Please submit your responses via the following link:

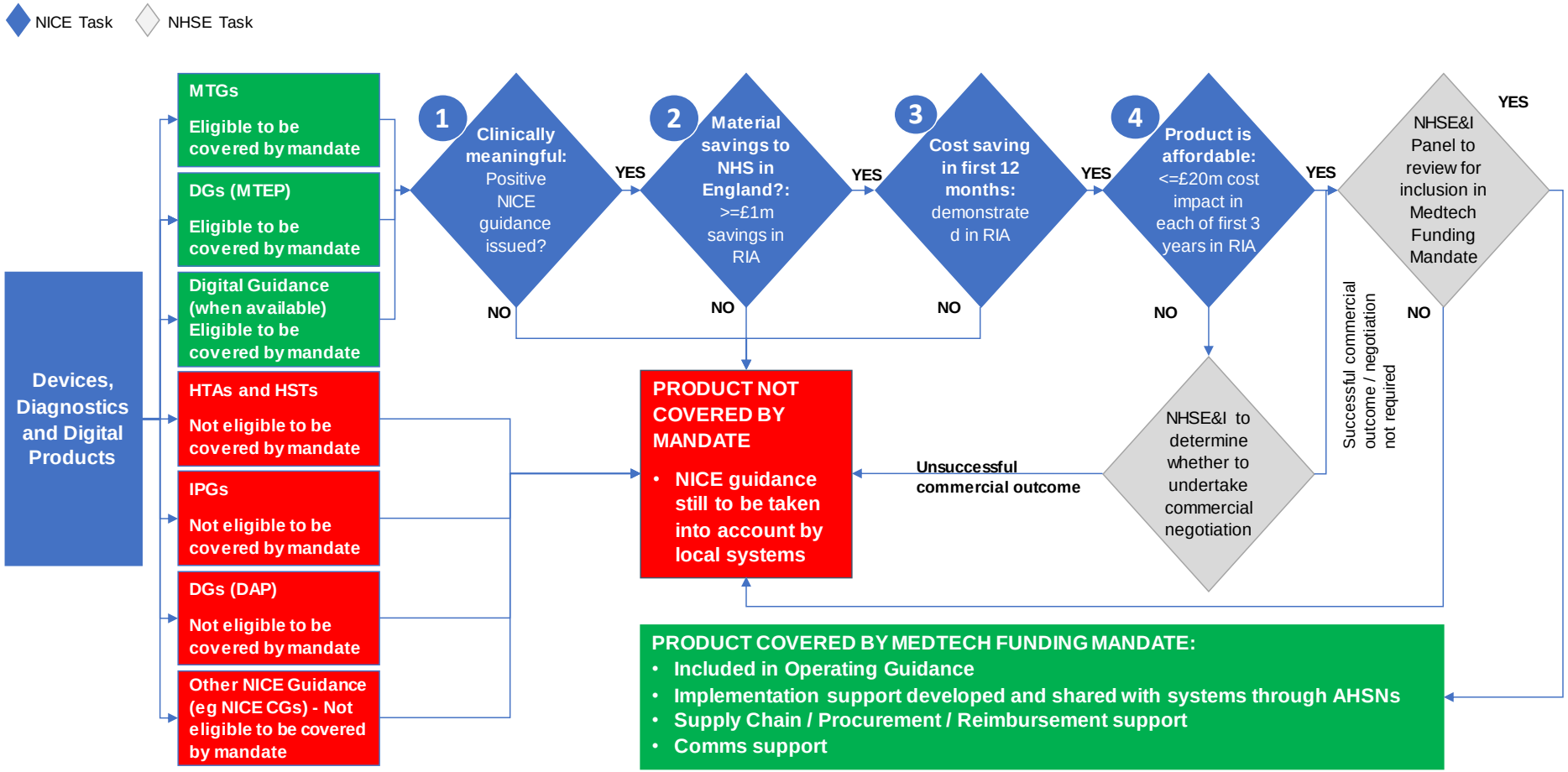
https://www.engage.england.nhs.uk/consultation/medtech-funding-mandate

Responses must be received by midnight on 18.12.2019.

Annex 1: Resource impact (5 year view)

Product	Savings (Y1) (£k)	Savings (Y2) (£k)	Savings (Y3) (£k)	Savings (Y4) (£k)	Savings (Y5) (£k)
SecurAcath (MTG34)	£848.00	£1,697.00	£2,545.00	£3,394.00	£4,242.00
HeartFlow (MTG32)	£1,826.00	£3,651.00	£5,477.00	£7,103.00	£9,128.00
PlGF (DG23)	£1,200.00	£1,800.00	£1,800.00	£1,300.00	£1,200.00
Total (for 3 products)	£3,874.00	£7,148.00	£9,822.00	£11,797.00	£14,570.00

Annex 2: How does product meet the proposed MedTech Funding Mandate Policy – process overview



Key: HTA: Health Technology Assessment | HST: Highly Specialised Technology | MTG: Medical Technologies Guidance | DG (MTEP): Diagnostics Guidance (Medical Technologies Evaluation Programme) | DG (DAP): Diagnostics Assessment Programme) | IPG: Interventional Procedure Guideline | NICE CG: NICE Clinical Guideline | RIA: NICE Resource Impact Assessment

Figure 4: How does and product meet the MedTech Funding mandate – process overview

Annex 3: Flow chart for determining whether an NHS organisation needs to comply with the Policy

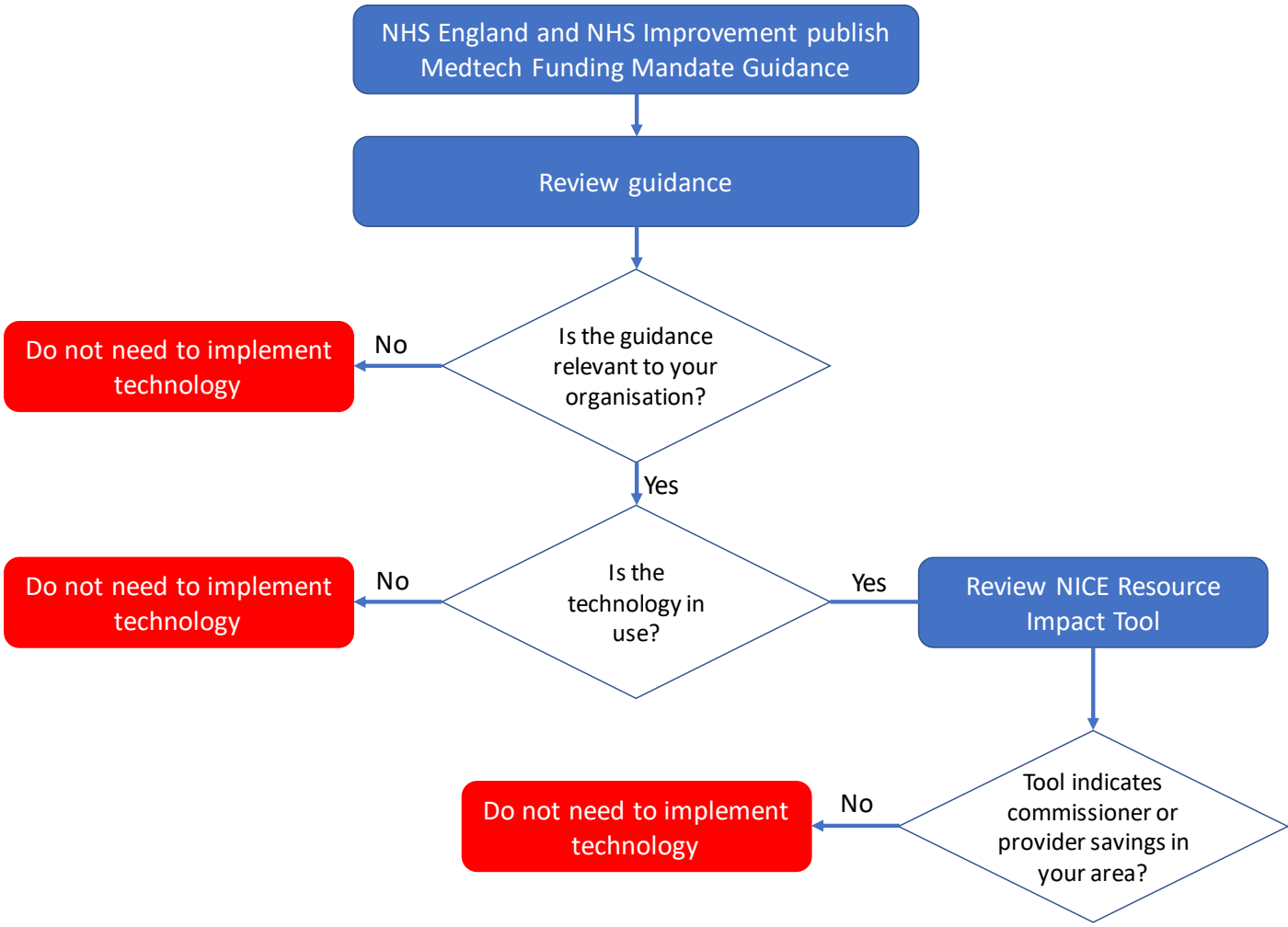


Figure 5: Flow chart for determining whether an NHS organisation needs to comply with the mandate

Annex 4: Implementation support for products covered by the proposed MedTech Funding Mandate Policy in 2020/21.

Product		
SecurAcath for securing percutaneous catheters (MTG34)	Link to NICE Guidance	https://www.nice.org.uk/guidance/mtg34
	Link to implementation resources -Resource Impact Report -Resource impact Template -Case Studies	https://www.nice.org.uk/guidance/mtg34/resources.
HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography (MTG32)	Link to NICE Guidance	https://www.nice.org.uk/guidance/mtg32
	Link to implementation resources -Resource Impact Report -Resource impact Template -Case Studies	https://www.nice.org.uk/guidance/MTG32/resources
PlGF based testing to help rule out pre-eclampsia (Triage PlGF test, Elecsys immunoassay sFlt-1/PlGF ratio) **(DG23)**	Link to NICE Guidance	https://www.nice.org.uk/guidance/dg23
	Link to implementation resources -Resource Impact Report -Resource impact Template -Case Studies	https://www.nice.org.uk/guidance/dg23/resources.