Consultation response – NICE/NHSE Medtech Pathway

Submit response here.

Section 1

1. In what capacity are you responding?
2. Are you responding on behalf of an organisation?
3. What is your name?
4. What is your email address?

Section 2: guiding principles

5. Are there any other important principles that should guide the development of an integrated, rules-based medtech pathway?

- One important principle is simplification. A major barrier to deploying new medtech solutions in the NHS is the current proliferation of parallel, partially-overlapping pathways. It can be confusing to both developers and adopters, who do not always know which pathway is most appropriate or efficient.
- For instance, in a roundtable discussion about the barriers to implementing AI tools in radiology, the RCR found that both adopters and developers struggle with the fact that there is no single information governance framework. Instead, each trust/health board has its own processes, such as their own Data Protection Impact Assessment (DPIA) forms. This slows down implementation; the lack of unity means extra work for developers and adopters in each deployment project.[1]
- Currently it is unclear to us whether the proposed medtech pathway would address this issue. Would the new pathway replace the current set of pathways? Or would it sit above them? Having a simpler system would be beneficial. NICE/NHSE should consider setting out where this new pathway would sit within the existing regulatory ecosystem.

6. What positive or adverse impacts could the integrated, rules-based medtech pathway have on protected characteristic groups and people at particular risk of health disparities? How do you think those impacts should be addressed?

- We believe that guiding principle 5 addresses the risk of medtech solutions inadvertently exacerbating health inequalities and disparities.
- Medtech solutions carry this risk. For instance, AI algorithms are only as useful as the quality of the data on which they are trained and tested. Should this data not adequately represent the actual population on which the algorithm is used, then there is a risk that the algorithm will under- or mis-perform with respect to individuals from certain demographic groups. If an AI tool designed to improve breast cancer detection rates from mammograms was only trained on data from largely white patients, then it may not perform as well in detecting potential breast cancers when used in clinical practice in areas with large numbers of Black and Minority Ethnic patients.
- The RCR has identified this risk and proposed solutions to it. These include creating the datasets needed to test and continuously validate algorithms used in the NHS, establishing audit frameworks for algorithms' performance, improving educational

[1] RCR (2023) *Overcoming barriers to AI implementation in imaging*. Available at: https://www.rcr.ac.uk/our-services/artificial-intelligence-ai/overcoming-barriers-to-ai-implementation-in-imaging/

resources available to NHS staff, commissioning research into AI's impact on patient outcomes, and more.[2]

- The risk can be generalised to all new medtech solutions: the context of their development may pose risks if it is inadequate to the context of their clinical use. Hence why Principle 5 is welcome.
- Nonetheless, further detail would be appreciated to set out how health disparities are not exacerbated in practice. Which individuals are responsible for this? How will risk be identified, quantified and evaluated? Will Principle 5 be expanded with further guidance to govern decision making?

Section 3 - part 1: key elements of the pathway

Pre-authorisation phase.

7. Do you agree that the timely and accurate provision of information by industry should be a pre-requisite for National Institute for Health and Care Excellence evaluation?

Strongly agree / Agree / Neither agree nor disagree / Disagree / Strongly disagree / don't know / Not applicable

Additional comments:

- NICE requires accurate and comprehensive data from developers to make thorough assessments of medtech solutions' clinical and cost effectiveness. This is in the interest of developers also, as well as patients, since it could increase the chances of their tool being purchased and speed up deployment times.
- Nonetheless, we acknowledge that for very early-stage medtech, the data available will be limited.
- We would like to stress that training data, however, is absolutely essential, and should be made a prerequisite for assessment. Information about the data on which a medtech solution was developed/trained is crucial for any evaluation of its clinical effectiveness and should not be overlooked.

8. How could all partners work with industry to ensure data coming from emerging innovations is robust and supports high quality horizon scanning?

- Where ensuring that robust data is shared, the most important factor to consider is the guidelines that set out what data must be provided; how this data should be collected; how up-to-date the data should be; adequate sample sizes required; how the data will be used; and so on.
- As mentioned in the previous answer, the provision of training data should be a prerequisite for assessment.
- Another enabling factor would be proactive engagement with industry from clinical partners, including from organisations like the RCR. This is important if we are to shape what medtech gets developed by signalling our requirements. We must ensure clinical and cost effectiveness by evaluating and adopting only those tools that the NHS

[2] RCR (2024) *Integrating AI into NHS diagnostics and cancer care services – regulation, governance and enabling factors. Briefing for the Science, Innovation and Technology Committee*. Available at: https://www.rcr.ac.uk/news-policy/latest-updates/accelerating-ai-deployment-into-nhs-diagnostics-and-cancer-care-services/

actually needs; bespoke tools for specific clinical tasks are far more likely to be cost and clinically effective than generic tools adapted to fit a healthcare context.

9. Should the Innovation Service provide any additional functionality to act as the 'centralised front door' for all innovative technologies in the NHS?
Strongly agree / Agree / Neither agree nor disagree / Disagree / Strongly disagree / don't know / Not applicable

Additional comments:

- The RCR supports the role of NHS IS here.
- To be of maximal value, NICE/NHSE must ensure that NHS IS *really is* the sole entry point for all innovative technologies.
- This relates to our answer to question 5, regarding simplification and unification of the whole system.
- Of maximal value would be NHS IS providing 1:1, step-by-step guidance to developers with a named liaison at each stage of the process. Alongside written materials, access to individuals who understand how to navigate the system and the new pathway would be invaluable to developers and would increase the chances of efficient progression of medtech solutions through the pathway.
- NICE/NHSE should therefore consider the capacity of NHS IS, in terms of staff and resources, to deliver such a service. Especially if there is a large wave of new medtech solutions coming to market in the next decade, can NHS IS match the demand there will be from developers to interact with the NHS and regulators?

10. How can stakeholders inform a shared understanding of the value of medtech to the NHS earlier in a product's development cycle?

- NICE/NHSE should set out clearly and at the outset what the NHS understands by 'value'. Developers should be able to access this, as well as the five guiding principles of the new medtech pathway.

11. How can all partners better signal demand to industry, academia, innovators, and investors? What information channels should NHS England, the National Institute for Health and Care Excellence and the Department of Health and Social Care use?

- NHSE should take the lead in terms of coordinating system partners to ensure the system as a whole speaks with one voice. This would ensure clear demand signalling to developers and academia.
- As mentioned in previous answers, having NHS IS as the sole entry point would be beneficial. NHS IS should be used as a venue for setting out clearly where the NHS has capability gaps that new medtech could fill.
- Would NICE/NHSE be able to specify what 8 medtechs have already been selected for the IDAP process? The technologies that have already been chosen for rapid assessment and deployment themselves are a powerful signal to industry in terms of what sorts of technology the NHS is looking to introduce.

Section 3 - part 2 : Key elements of the pathway
Evaluation and guidance phase.

12. What additional factors should NHS England, the National Institute for Health and Care Excellence and the Department of Health and Social Care consider when selecting technologies and categories of technologies for the pathway?

- We agree with the core factors that NICE/NHSE have identified: meeting an existing lack, clinical effectiveness, cost-effectiveness, affordability, health inequalities, and the environment.
- However, further details on some of these factors and how they will be managed would be welcome. In particular, there was little detail in the consultation document on health inequalities and environmental sustainability.
- NICE/NHSE should also address how the factors will be balanced as and when they come into conflict. Do they have equal weighting? If not, when and how will some be prioritised over others?
- The RCR would register a concern that the EVA process, as it stands currently, is too slow to keep pace with the number of new medtech solutions being made available. For instance, there are tools being rolled out via national AI deployment projects currently that have not yet undergone EVA.
- NICE should continue to work collaboratively, as they have been doing, with medical Royal Colleges and other professional bodies to identify medtech that would warrant EVA or MTG review.[3]
- NICE/NHSE should consider providing further details on how decision-making with regards to which technologies are chosen for MTG (versus EVA) are to be chosen. Likewise, at what point it is decided a medtech is moved from EVA to MTG, and when it is moved from MTG to LSA.
- NICE/NHSE should set out how the budget impact figure of £10m/yr was arrived at and justify this threshold. Does this figure pertain to the central NHSE budget, or to the budget of the individual trust/health board or network looking to adopt the medtech? Would this figure apply to existing medtech already in use, but for which we do not currently have sufficient evidence of cost-effectiveness? Answers to these questions would be beneficial.
- When selecting technologies for the pathway, the following additional factors could be considered:
    - How the medtech changes clinicians' ways of working. E.g. with AI tools in diagnostics, it is an open question the extent to which they will speed up radiologists' ability to process scans and make diagnoses. Likewise, it is not certain where and how any time that is freed up will be used?[4]
    - Ethical considerations, such as the use of patient data and the preservation of anonymity and privacy when using patient data to test or train a tool.

13. How can products that receive a positive early value assessment recommendation best be supported to develop evidence?

- Professional bodies such as the RCR have a role to play in post-market surveillance of medtech recently introduced to the NHS. Clinical expertise will be essential in the

[3] RCR (2024) *Embracing AI to support the NHS in delivering early diagnoses: Report from a meeting at 10 Downing Street, 30 October 2023*. Available at: https://www.rcr.ac.uk/news-policy/policy-reports-initiatives/embracing-ai-to-support-the-nhs-in-delivering-early-diagnoses/

[4] Ibid.

evaluation of medtech solutions' ongoing performance, and professional bodies are best placed to coordinate and deploy that expertise.

- NICE/NHSE should develop clear guidance for developers and adopters in order that both groups know what evidence is required.
- There should be a centralised, national data collection so that when a medtech tool is successfully adopted into practice in one NHS site, it can be swiftly adopted in other sites. This would prevent duplication of labour and ensure evidence is available to all potential adopters. NICE/NHSE should consider utilising the expertise of organisations like the RCR, which has extensive experience with auditing healthcare, to deliver this.

14. To what extent do you think there is an opportunity to streamline existing innovation funding streams to provide a more systematic approach to supporting conditional reimbursement for early value assessment recommended medtech?

- There is significant potential for streamlining funding streams. Currently, there are multiple streams, which can make funding hard to identify and access.
- Funding streams currently are also mostly discrete and fixed-term. This limits market confidence that adoption is likely, which slows the rollout of innovative technologies. For example, for AI in diagnostics, the AI Diagnostics Fund and the AI Deployment Platform are fixed-term initiatives; there is currently no certainty as to where funding will come from after their end.
- Similarly, funding streams' timeframes are also too short, currently. They have a tight window to apply, implement and assess medtech. This means that project planning is rushed and the output data and benefits are limited.
- Relatedly, NICE/NHSE must ensure they learn lessons from projects like the AIDP/AIDF processes – not just in terms of implementation, but also in terms of the funding approaches taken.
- A more limited number of streams, which are clearly signposted and accompanied by clear guidance, would be beneficial.

Section 3 - part 3: key elements of the pathway

Commercial and commissioning phase.

15. Do you envisage the proposed commercial activities will help the NHS to maximise value for money from new medtech?

Strongly agree / Agree / Neither agree nor disagree / Disagree / Strongly disagree / don't know / Not applicable

Additional comments:

- The proactive measures identified in the consultation document, such as identifying available funding sources and providing resources to commissioners/adopters, will be beneficial
- However, more detail would be beneficial.
- As part of the LSA, NICE/NHSE should set out further details on how frequently medtechs will be assessed. Post-market surveillance will be essential, and as part of this we need to continuously validate clinical performance and reassess cost-effectiveness. Some framework for this is ultimately needed.

- For example, one risk of deploying AI tools is model drift. If something in the AI tools' environment changes, then this may cause the performance of the AI tool to change, potentially to the detriment of patients. This necessitates some form of surveillance to ensure the AI continues to perform as it did in testing and as is expected.[5]
- NICE/NHSE should consider whether much of the commercial and commissioning phase would be best done centrally, rather than at ICB level. A national-level approach would help accelerate deployment across whole England and smooth out variation between sites in terms of the medtech available.

16. Please provide comments on what, if any, other commercial mechanisms/activity NHS England and the National Institute for Health and Care Excellence should consider to maximise value for money from medtech through the pathway.

- NHSE should work with imaging networks to increase the practice of centrally commissioning diagnostic equipment, especially where next-generation scanners are concerned.[6] Doing so would enable cost savings to be made via bulk purchasing, as well as planning of services at the regional level to meet patient needs.
- NHSE should also consider how it can encourage trusts to use NHS Supply Chain and how it can support NHS Supply Chain to offer the best value for money to trusts when it comes to purchasing equipment and technologies. There are reports that trusts are avoiding NHS Supply Chain, which may be because they are able to find a better deal elsewhere.[7]
- More broadly, NHSE may wish to consider rationalising procurement frameworks in general to ensure trusts understand how to acquire equipment and technology in the fastest and most cost-effective manner.

17. What further work could help to inform an understanding of the value of medtech to support sustainable commissioning, funding, and adoption through the pathway?

- Further detail would be appreciated on the proposals set out in the scaled adoption phase. In particular, with regards to the proposal made in 3.57 of the consultation document, it would be good if NICE/NHSE could set out how new medtech will be embedded in specialised service specifications. Will this process be conducted via consultation? The RCR believes it would be essential for clinicians to be able to feed into any updates to their service specifications.
- We would also like to raise a concern about the relatively little level of clinical input that appears to have been built into the proposed medtech pathway. Clinicians are best placed to advise on how new technologies could be used most effectively with regards to clinical outcomes. NICE/NHSE should set out how they will obtain and use clinical input as part of the new medtech pathway.

[5] Ibid.
[6] RCR (2024) *Equipped for the future: Diagnostics equipment in NHS England – the case for investment*. Available at: https://www.rcr.ac.uk/news-policy/policy-reports-initiatives/equipped-for-the-future-diagnostics-equipment-in-nhs-england-the-case-for-investment/
[7] UK Parliament (2024) 'NHS missing out on tens of millions of procurement savings, PAC report warns', 27 March. Available at: https://committees.parliament.uk/work/8140/nhs-supply-chain-and-efficiencies-in-procurement/news/200612/nhs-missing-out-on-tens-of-millions-in-procurement-savings-pac-report-warns/