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Submitted to Building an integrated, rules-based medtech pathway
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About you

1 In what capacity are you responding?

Other

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On behalf of an organisation

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Yes

If you have selected 'yes', which organisation are you responding on behalf of?:
Responsible Ai UK

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Section 2: guiding principles

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

Please provide comments:

The Responsible AI Health and Social Care Working Group would like to recommend the following:
1. The pathway should integrate the principles of responsible research and innovation (RRI). This ensures that not only benefits but also potential harms are considered from the outset, as well as long-term impacts and sustainability issues. We believe that this is especially important when considering emerging technologies, such as large language models, where outcomes and uses are evolving within healthcare and with regards data access and how this data is used by different stakeholders.
2. The pathway must consider not just clinical and cost effectiveness, but the potential for products to be scaled within the healthcare system. There are many examples within healthcare of failure, although we may be more aware of the successes. This should also consider the specific applications where it is currently scaled and other areas where it may offer benefits. One example is robotic assisted surgery (RAS) which has proven to be extremely effective in scaling minimally invasive surgery to nearly 90% in urology whilst others have much lower rates of scale, for example in major cancers (colorectal, lung, uterine) where minimally invasive surgery remains around 60-70%.
3. Inputs to define and direct efforts towards technologies of interest. Do we need to set out explicit principles to guide horizon-scanning in the pre-authorisation stage? Specifically about what is meant by "most promising" [technologies]. The most promising technologies are surely those which set out to meet the most acute unmet needs (of patients) or requirements. If it were possible, a guiding principle on what the greatest unmet needs/requirements are would be valuable to both care providers and technology providers.
4. We agree that the pathway should also ensure clear communication and transparency with patients and the public, alongside health and social care stakeholders. This is especially important where emerging technologies with complex functions, such as artificial intelligence, are being deployed. Consideration of patients should be central, e.g., through patient and public involvement or patient reported outcome measures. Medtech composed of particularly complex technologies, such as artificial intelligence, may sometimes be challenging to explain or describe to laypeople. There is a tendency to exclude laypeople or to restrict communication in these instances. We argue that it is essential that the pathway recognises the impact of public perceptions and integrates ways of ensuring clear communication with wider patient and public communities. History has taught us that this is important, e.g., in the public response to care.data https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4880636/ (Sterckx S, Rakic V, Cockbain J, Borry P. "You hoped we would sleep walk into accepting the collection of our data": controversies surrounding the UK care.data scheme and their wider relevance for biomedical research. Med Health Care Philos. 2016 Jun;19(2):177-90. doi: 10.1007/s11019-015-9661-6. PMID: 26280642; PMCID: PMC4880636.). This may require more interdisciplinary approaches to public engagement and science communication.
5. Finally, the pathway should promote insights on successful implementation and effective stewardship of solutions. Technology must not be reduced to 'devices', but should take a systems approach to identifying and guiding factors for successful implementation— this is particularly true for AI, where the infrastructure and service models within which AI is deployed have a significant impact on the value it confers. Lessons can be learned from existing programmes of work e.g., within NICE.

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?

Please provide comments:

The Responsible AI Health and Social Care Working Group would like to ensure that the NHS reflects on the inequalities that an integrated pathway may have. Integrated pathways may have a negative impact on minority groups, including those with rare conditions, where there is minimal commercial value even when there may be a greater health benefit for these patients. We argue that datasets may lack diversity, be biased or under-representative, and so not be able to fully represent the value especially to underserved communities. We support an approach that adopts mitigations, such as incentives for technologies that address these groups or are more inclusive, and that companies are asked to report any potential biases or exclusions within their applications. There should also be a focus on whether the evidence they present is diverse and representative, ensuring that those with protected characteristics are included.

Section 3 - part 1: key elements of the pathway

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?

Agree

Please provide any additional comments:

The Responsible AI Health and Social Care Working Group feels that there is a need not only for timely and accurate provision of information by industry but also clear guidelines on the process required. This will provide assurance in the valuation itself as well as supporting verification of the information provided by industry. We recommend that existing frameworks could offer guidance for industry, including the IDEAL framework for surgical robotics https://www.nature.com/articles/s41591-023-02732-7 (Marcus, H. J., Ramirez, P. T., Khan, D. Z., Layard Horsfall, H., Hanrahan, J. G., Williams, S. C., ... & Additional collaborators Sedrakyan Art 63 Horowitz Joel 64 Paez Arsenio 65. (2024). The IDEAL framework for surgical robotics: development, comparative evaluation and long-term monitoring. Nature medicine, 30(1), 61-75.) along with standards such as BS 30440:2023 or DCB0129. This can support industry in developing from a minimally viable product to one that can fit within the health and social care system and allow for products at various stages of development to benefit from engagement with the integrated pathway.

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

Please provide comments:

We would like to refer to the previous question and our suggestion of using existing frameworks and standards that can provide guidance for industry to ensure data is robust. The use of collaborative data platforms can help stakeholders to share data within safe and secure ways, particularly where there are standardised protocols for data collection to ensure consistency. Additionally, learning from other initiatives like the EPSRC Digital Health Hubs, EPSRC Quantum Hubs, and EPSRC Health can provide easily replicated platforms and processes.
https://www.ukri.org/wp-content/uploads/2023/03/EPSRC-23032023-health-technologies-strategy-Final.pdf
https://www.ukri.org/news/five-hubs-launched-to-ensure-the-uk-benefits-from-quantum-future/
https://www.hdruk.ac.uk/study-and-train/about-the-training-team/impact-and-partnerships/digital-health-hub-partnerships/

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

Please provide any additional comments:

Historically, HealthTech Connect also provided a centralised front door but it was at times unclear for industry when they should engage and there was a lack of connection with academia and wider stakeholders. We would also suggest that the Innovation Service needs to be more proactive in ensuring that industry is aware of their role and encouraging them to engage. The Responsible AI Health and Social Care Working Group thinks that the Innovation Service taking on this role is a good idea and will help to streamline processes, providing a single point of reference for medtech. The opportunity here is to ensure that information and guidance is centralised also, with pathways to other organisations as needed (e.g., MHRA). It is possible that domain experts will be needed, particularly for complex applications of emerging technologies, where additional requirements may be difficult to identify. For example, machine learning is increasingly being used on brain scans for diagnostic purposes. If brain scans are being increasingly accessed and shared, there may be privacy risks if these images are not adequately anonymised; it is possible that people could be identified from their brain scan alone without privacy-preserving measures in place. The RAi AI Champions Programme (https://rai.ac.uk/events/ai-for-healthcare/) and the RAi Health and Social Care Working Group (https://rai.ac.uk/working-groups/health-and-social-care/) offer a potential solution not just in providing expertise but also opening doors to unconnected industry actors.

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

Please provide comments:

NHS business cases do not always rely on cost-effectiveness but have many broader elements in terms of value. Whilst a cost benefit analysis early in the development cycle is optimal, this can only happen where there is access to the data needed. Considering the disparity in data within the NHS (including disparity in access e.g., industry vs academia, medical fellows vs computer scientists) it is not always possible. The Responsible AI Health and Social Care Working Group suggests that a focus on value is embedded as early as possible, aligning also with RRI practices such as stakeholder engagement and multidisciplinary workshops and consultations. Considering the remit of ICBs, there is potentially an argument for additionally considering the broader societal perspective – there is an opportunity now for the Innovation Service to consider this. Accelerator programmes, particularly involving

interdisciplinary stakeholders, could also offer a route to better understanding of the value of medtech. For example, NHS and AI stakeholders could evaluate proposals and provide multi-perspective insights into the potential success.

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?

Please provide comments :

The Responsible AI Health and Social Care Working Group suggests that the Innovation Service works more proactively with UKRI and NIHR as the main funders of Medtech, to ensure there is cross-disciplinary involvement in setting up grants and it can also provide an additional information channel for better signalling of demand. We also encourage engagement with larger programmes such as Responsible AI to influence and help prioritise their funding calls and research strategy, as many of the emerging technologies that could evolve into medtech opportunities will emerge from research initiatives within these UKRI programmes . Ensuring that there is additional capacity within organisations such as NICE to allow for collaboration is recommended.

Section 3 - part 2 : Key elements of the pathway

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?

Please provide comments:

The Responsible AI Health and Social Care Working Group recommend that the following additional factors are considered:
1. Workforce: It is important to address whether digital skills and literacy are sufficient within the NHS workforce to accommodate the medtech, including whether additional training might be needed and how this will be provided. This is especially true of newer and emerging technologies. For example, in robotic assisted surgery there may be additional skills or roles provided e.g., a surgical care practitioner as assistant.
2. The societal perspective may benefit patients with protected characteristics and/or rare diseases more, meaning the impact of investment is felt more broadly within these communities.
3. Additional factors that are more familiar to those working in technology, such as security, should also be included. As with the example earlier provided of how brain scans could be used to identify patients, it is essential that unintended consequences are mitigated where possible. This requires an interdisciplinary perspective that can be guided by RRI activities.

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

Please provide comments:

The Responsible AI Health and Social Care Working Group suggest that guidelines and frameworks are provided with e.g., established protocols such as AI sandboxes or shadow trials which could be used to assess early adoption or engagement, as well as potential risks. The parameters for early evaluation should also be clearly defined e.g., identification of need, safety, clinical and cost effectiveness, scalability, clinical pathway impact, and workforce needs. Additional support such as funding to enable participation in sandboxes or trials would also be of benefit.
It is important that NHSE and NICE also liaise with funders. Evidence generation can be more or less costly, depending on the target condition, population, technology. Additionally, it may be that specific areas need to be addressed that could be supported by funders e.g., where larger or more diverse participant populations are needed. Consideration is needed of the sustainability of industry during these processes, especially if recommended only for research. Some may be unsuccessful and there are frameworks such as NASSS that can support industry in mitigating this. However, it is also clear that early innovators are at a disadvantage. For example, those that follow may be able to use their evidence to demonstrate equivalency rather than having to engage in lengthy and expensive clinical investigations. Support for early innovators should be available through funding that links closely with the early value assessment.

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?

Please provide comments:

Ideally, the main funders, such as UKRI and NIHR, and the Innovation Service would work in tandem to streamline funding. This is particularly important as there are several examples of medtech products arising from EPSRC rather than more medical or clinical funders. Ideally, the funding would align to early value assessments and ensure that innovations are funded which have a clear pathway to adoption and add value to the health and social care system. Clarity about what constitutes the necessary pathway for these products, what evidence is needed, and what is likely to be adopted could help funders ensure better outcomes for their investment. Larger multi-disciplinary and multi-institutional consortiums, perhaps jointly funded by different funders, could lead in identifying new funding streams and help support horizon scanning through close collaboration with the NHS, NICE, and Innovation Service.
There is also potential for greater sharing of infrastructure and more collaboration across institutions. For example, several universities already have data storage and compute facilities and have already developed test environments that could be re-used.

Section 3 - part 3: key elements of the pathway

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

Agree

Please provide any additional comments:

The Responsible AI Health and Social Care Working Group feel that the integration of commercial activity within these ventures will encourage more proposals to be scaled through the NHS rather than losing business to other markets such as the USA. It is important to consider the value of the UK's SME sector and ensure that they are not costed or negotiated out of being competitive against larger organisations or those with a more secure market share (often in private healthcare systems such as the US). Investment early may be higher, particularly where emerging technologies are concerned (e.g., high early costs for AI model training), but with a greater potential for benefit realisation later; this may require higher up-front costs to be agreed. It is also important to note that several potentially disruptive products are not yet part of the UK medtech strategy, including robotic assisted surgery. This is despite the fact that a third of NHS spend is on implants and prostheses, and surgical equipment which accounts for 17% and 16% respectively of annual spend in the UK on medtech.

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.

Please provide comments:

expanding successful ventures to other countries e.g., the US, EU and beyond. This could potentially include information or guidance on standards, regulations, and relevant legislation. Additionally, considering the scalability of medtech, we would also encourage NHSE and NICE to consider the potential for more national commissioning opportunities to benefit from the economies of scale. Although the NHS App Libraries have been unsuccessful, a similar model for medtech may be an option. This could utilise the centralisation that is done for the Innovation Centre and bring together the dynamic purchasing systems, DTAC, and digital marketplace to focus on a medtech offer.

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?

Please provide comments:

The idea of real-world evidence generation has been addressed previously within UK policy and the Responsible AI Health and Social Care Working Group would encourage consideration of this as a way to inform the understanding of medtech's value. Promoting existing medtech ventures that have clear potential could provide case studies and this would also offer an opportunity to explore any barriers to adoption. Additionally, a more national approach is needed in several areas including training, commissioning, and funding. For example, there is no national surgical training programme so although there is accreditation from bodies such as the Royal College of Surgeons e.g., in robotic assisted surgery using specific tools, these are not currently formalised across the UK. As stated previously, national commissioning could bring economies of scale in medtech. On the one hand, funding for clinical investigations/innovations is often centred on the Shelford Group of NHS Trusts and Russell group universities, often urban, and often in the South of England. This biases outputs; it is unclear whether wider rollouts of medtech will bring the same benefits when evidence is generated in narrow populations. We recommend that evidence generation takes into consideration a more national approach that is representative across populations, geographies, locales. Additionally, emerging technologies offer the medtech sector the potential for far more specific and targeted solutions but accepted or gold standard methodologies in healthcare (e.g., RCTs) are not well-suited. Further work should address new methodologies that can support evidence generation for transdiagnostic medtech products.