Board meeting

11 December 2024

HealthTech Manual

Purpose of paper

For approval

Board action required

The Board is asked to consider this manual and approve it for public consultation in February.

Brief summary

This paper provides the first section of the HealthTech manual introducing new approaches and structures following the transformation of HealthTech at NICE to be simpler and more user focused.

Over the last few years, NICE has transformed its approach to HealthTech and this manual consolidates the programme developments in design, methods and processes for public consultation. Informed by consultation, this new approach will become the substantive HealthTech Programme at NICE.

Board sponsor

Mark Chapman, Director of Medical Technology

Introduction

1. HealthTech products and interventional procedures can offer significant benefits to patients, such as a quicker diagnosis, faster recovery, and reduced risk. They also have potential to improve efficiency, such as by streamlining patient flow, tailoring treatments to an individual, and reducing hospital admissions.
2. HealthTech is vital to delivering the 3 big shifts needed in the NHS, as outlined by government this year: from hospital to community; from analogue to digital; and from treating sickness to prevention.
3. In light of advances in life sciences and technology, and the different demands on the health and care system, NICE has simplified its approach to HealthTech assessment and strengthened its partnership working to enable greater flexibility in assessment and increase its ability to respond to the needs of patients and the health and care system.
4. This manual describes the methods and processes that NICE follows when evaluating interventional procedures and HealthTech products. The methods and processes are designed to produce robust guidance for the NHS in an open, transparent and timely way, with appropriate contribution from stakeholders.

Background

1. This first section of the manual describes key developments that need to be implemented to reduce the risk of challenge to guidance and to ensure NICE can be responsive if evaluations are requested.
2. The key changes to the HealthTech manual are:
	1. Merging the Interventional Procedures Programme, Medical Technologies Evaluation Programme and Diagnostics Assessment Programme to be one HealthTech Programme
	2. Creating a single shorter and longer process (determined by the level of economic modelling required) that applies across all evaluations (healthtech products and interventional procedures) in the HealthTech Programme to remove existing multiple processes from the 3 previous programmes
	3. Setting the multi-tech evaluation and cost-effectiveness as standard for HealthTech, removing the cost-saving remit and single tech assessment approach of the Medical Technologies Evaluation Programme. Multi-tech guidance is more useful to the NHS because it increases patient and clinical choice, improves resilience in supply, supports a competitive market and more usefully informs NHS procurement. Cost and resource saving will still be shown in evaluations but removing the cost-saving remit allows health economic assessments of value to be more clearly separated from resource impact assessments and NHS finance.
	4. Removing the use of Specialist Committee Members and using expert advisers as standard across programme. This will enable Committees to have full discussions transparently in the open forum. We will ensure sufficient clinical input by reviewing our standing committee composition and by increasing engagement with clinical academics who may wish to help with evidence generation.
	5. Describing the final methods for assessing technologies for early use (previously early value assessment) and the production of evidence generation plans.
	6. Describing the lifecycle approach and removing reference to the specific pilot initiative, Early Value Assessment. HealthTech products and procedures can now be assessed for early use, for routine adoption and for review when in existing widespread use.
	7. Guidance on HealthTech products will now be named HealthTech Guidance (HTG) rather than Medical Technologies Guidance and Diagnostics Guidance. Interventional Procedures Guidance will remain in name as it is stated in the NHS constitution. The benefits and risks of changing this name to HealthTech guidance will be explored with legal advice in Q4 2024/25.

Next steps

Subject to approval, this manual will be released for public consultation in February 2025.

1. Clear communications will be provided for stakeholders to explain our approach to the manual update and an implementation plan will be developed for enacting the changes operationally.
2. A further update including economic analysis for interventional procedures and possible changes due to late stage assessment and partnership working such as commercial considerations, will be delivered in early 2025/26 business year. After these two substantial updates, it is expected that HealthTech will move to smaller more focussed regular updates.

Cross organisational impact

1. To prevent any duplication of, or inconsistency with, information in the CHTE or Interventional Procedures manuals, minor amendments to these documents are proposed. Some interim documents which will be superseded by the HealthTech manual are also proposed for archiving:
	1. Early value assessment interim statement (PMG39)
	2. Interim addendum on guidance reviews
	3. Interim addendum on scoping workshops
2. This manual describes areas that are different for HealthTech and refers to the CHTE manual where processes and methods are the same, to avoid duplication.
3. By updating in this way, HealthTech will have one set of methods and processes across its 3 programmes which will make future alignment across Clinical Guidelines and Technology Appraisals to one NICE manual easier.

Board action required

The Board is asked to:

* 1. Approve this manual for consultation

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