NICE National Institute for Health and Care Excellence

PMG39 Early value assessment interim statement: appendix 1

15 December 2022

Abbreviations

AAC	Accelerated Access Collaborative
AHSN	Academic Health Science Network
CE	European conformity assessment mark
CQC	Care Quality Commission
CSO	Central Statistics Office
DAC	Diagnostic advisory committee
DAP	Diagnostics Assessment Programme
DDD	Devices, Diagnostics and Digital
DHSC	Department of Health and Social Care
DTAC	Digital Technology Assessment Criteria
H&SC	Health and Social Care
HTW	Health Technology Wales
IAPT	Improving Access to Psychological Therapies
ICS	Integrated Care System
IDAP	Innovative Devices Access Pathway
MTAC	Medical technology advisory committee
MTEP	Medical Technology Evaluation Programme
NCDs	National Clinical Directors
NHS	National Health Service
NHS SBS	National Health Service Shared Business Services
NHSE	National Health Service England
NHSE/I TD	National Health Service England and Improvement Transformation Directorate
NICE	National Institute for Health and Care Excellence
NIHRIO	National Institute for Health and Care Research Innovation Observatory
OCSC	Office of the Chief Scientific Officer
RWD	Real-world data
SCM	Specialist committee members
SHTG	Scottish Health Technologies Group
TI	Topic intelligence
UKCA	UK Conformity Assessment
XR	X-ray

Figure A: Main functions of topic intelligence

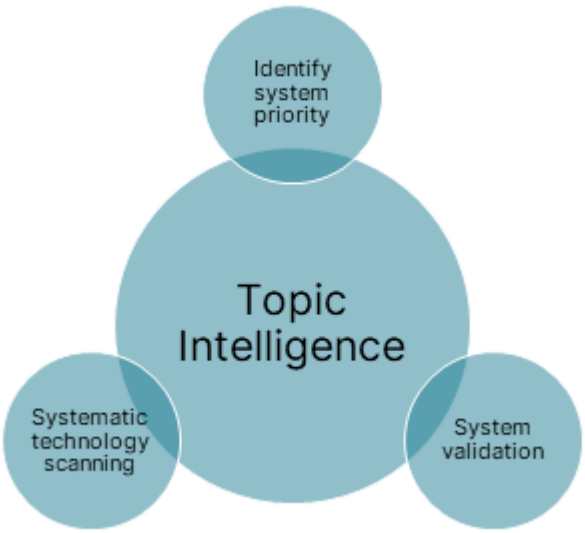

Table 1 Examples of Engagement groups for intelligence

Function	Source/engagement	Output	Comment
Policy	DHSC, NHSE NICE Strategy Team, H&SC AAC NHSE TD Digital Policy and Digital Investment Teams Office of the Chief Scientific Officer (OCSO) Health Charities e.g., King's Fund Local Government Association NHS SBS	Signal of current policy drivers and priorities for NHS and social care systems	Ensures alignment of NICE to national policy drivers
Clinical need	AAC NHSE/I TD NCDs AHSNs ICS innovation teams Royal Colleges Voluntary and community sector organisations	Signal of unmet clinical need, described as diagnostic, therapeutic, access, AND amenable to support by DDD solution	Ensures NICE is working with the system to support patients and staff

Function	Source/engagement	Output	Comment
	Academia		
Technology	NICE internal NICE Information Searches AHSN network NHSE programmes, e.g., IAPT, XR, Cancer, etc NHSE Innovation Service NHSE/I TD Royal Colleges Voluntary and community sector organisations Professional Societies HTW and SHTG Trade associations Industry leaders Academia Conferences DDD news outlets NIHRIO DDD Office of the CSO	Technology products which are suitable for review by NICE, to be documented in the TI database and triaged accordingly	Multiple feeds available for technology, different quality of outputs, information governance constraints must be considered for topics shared with NICE.
Reimbursement	NHSE/I TD Commercial Unit DHSC NHS SBS	-	-

Table 2 Filtering criteria for topic areas and technologies

Criteria	Description
Topic Priority	Technology falls in a priority area for the health and care system
Platform	Lists the platform(s) that the technology operates on, e.g., mobile, desktop, cloud-based
Regulation	CE/UKCA mark, DTAC, CQC registration
Funding	Product linked to a currently funded work programme
Current usage	Technology is currently in use within the health and care system, aligns to NICE or national guidelines, fits a clinical pathway, and articulates a positive impact on the pathway
Evidence	Benefits to patients, and/or the system, and is in a published format.
Other	Environmental sustainability, workforce impact, inequalities, RWD and data collection issues captured.

Table 3 Test and learn approaches to the early value assessment pilot technologies (1/2)

Topic	Scoping	Assessment	Committee/panel	Consultation	GE	Resolution
KardiaMobile 6-Lead (single technology)	Standard 16 week DAP scope process	20 week assessment including 16 week clinical gap analysis 4 week cost report	DAC and SCMs	2 weeks	Yes	2 weeks (factual inaccuracies only)
CYP guided self-help CBT (multiple technologies)	8 weeks consultation followed by scoping workshop	4 weeks Clinical gap analysis and attempting value of information modelling	Panel with SCMs	2 weeks	To be decided	No
CaRi-Heart (single technology)	8 weeks Scoping workshop without consultation	8 weeks Clinical gap analysis with basic economic	DAC and SCMs	2 weeks	Yes	No
Digital therapies for adult depression (multiple technologies)	8 weeks workshop followed by consultation	8 weeks Clinical gap analysis Basic economic analysis (potential for conceptual modelling)	MTAC or panel (and SCMS)	2 weeks	Likely	No

Table 4 Test and learn approaches to the early value assessment pilot technologies (2/2)

Topic	Scoping	Assessment	Committee/panel	Consultation	GE	Resolution
Digital therapies for adult anxiety (multiple technologies)	8 weeks workshop followed by consultation	8 weeks Clinical gap analysis Basic economic analysis (potential for conceptual modelling)	MTAC or panel (and SCMs)	2 weeks	Likely	No

Topic	Scoping	Assessment	Committee/panel	Consultation	GE	Resolution
Genedrive MT-RNR1 ID (single technology)	Standard 16 week DAP scope process	8 weeks Systematic review of clinical and cost effectiveness evidence and development of an economic model	DAC and SCMs	2 weeks	To be decided	No
ProKnow (single technology)	8 weeks consultation followed by scoping workshop	8 weeks Clinical gap analysis Basic economic analysis (potential for conceptual modelling)	MTAC and SCMs	2 weeks	To be decided	To be decided

Figure B: Flow chart illustrating decision making considerations

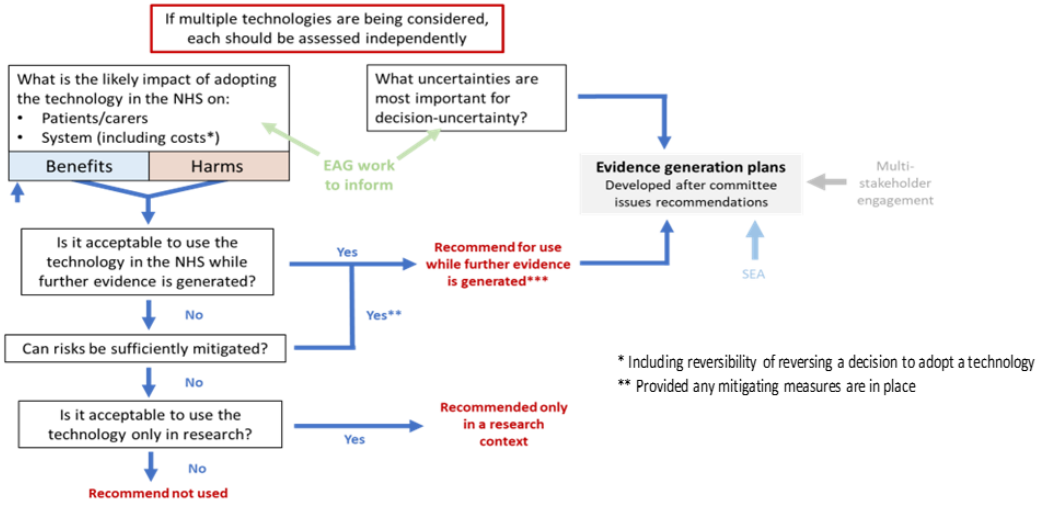

Table 5 Principle to guide approach to evidence generation for medical technologies

Principle	Description
1	Early engagement with NICE, produces greater opportunities for stakeholders and health system partners to understand and support further evidence generation for promising new technologies.

Principle	Description
2	Evidence generation plans will be informed or guided by NICE's real-world evidence framework, the evidence standards framework for digital health technologies, expertise, and experience from the managed access approach for medicines, and the Commissioning through Evaluation programme for medical technologies.
3	The early value assessment evidence generation approach is an assessment of research done to date, gaps in the evidence and factors that have contributed to these, resulting in a proposal for proportionate options to guide further data collection and analysis.
4	Technology developers will take a leading position to pursue opportunities for evidence generation with the support of NICE.
5	NICE will provide support and guidance about evidence generation and broker relationships with stakeholders and partners who can support adoption, use, data collection and analysis.
6	Multistakeholder collaboration will be key to developing evidence generation plans.
7	Evidence generation plans will identify what further data needs to be collected, how it could be collected and analysed and how this data collection will support a future NICE guidance.
8	Real-world data collections should build on existing clinical information flows.
9	Evidence generation should be for the shortest time necessary to collect the data needed to sufficiently resolve uncertainties in the evidence.
10	The additional burden of any new real-world data collection must be proportionate to the evidence gap it will address.
11	The technology developer/data or study lead is responsible for making the evidence generated through early value assessment available to NICE in a form that can be used for decision making as part of a guidance update.

ISBN: 978-1-4731-4818-5