NICE National Institute for Health and Care Excellence

Evidence standards framework for digital health technologies: user guide

Implementation support

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What are digital health technologies?

Digital health technologies comprise a wide range of products used in the health and social care system, including apps, software and online platforms that are intended to benefit people or the wider health and social care system. They may be standalone or combined with other products such as medical devices or diagnostic tests.

Digital health technologies have the potential to empower people, allow more convenient care, reduce numbers of appointments, and help people who may be isolated from standard care. They are often highly scalable with low costs.

For the purposes of the evidence standards framework, digital versions of medical textbooks, teaching aids or similar resources are not considered to be digital health technologies.

The evidence standards framework is designed to be used for digital health technologies that are being considered for commissioning in the UK health and social care system.

The framework

Why was the framework developed?

Evaluating digital health technologies in terms of their potential user and system benefits is challenging.

Digital health technologies are rapidly developed and updated with new versions being regularly released. There is generally less or lower quality evidence for digital health technologies compared with the evidence available for drugs or devices. This is because of how quickly they are developed, and the challenges faced by smaller technology companies in accessing clinical trial expertise and research funding. Also, there are specific issues with digital health technologies around data security, privacy and confidentiality, which are difficult to assess by non-specialists.

These challenges have created barriers to digital health technologies being commissioned and inconsistencies across the UK in how these commissioning decisions are made.

The framework was developed to provide a set of evidence standards that should be used to show the value of digital health technologies in the UK health and social care system.

NICE has been commissioned to produce this framework in order to support principle 11 of the Department of Health and Social Care's guide to good practice for data-driven health technologies (generate evidence of effectiveness for the intended use and value for money) but it will also be relevant for other principles.

What is the aim of the framework?

The framework describes the types and levels of evidence needed to show the effectiveness and expected economic impact of a digital health technology. It aims to establish consistent criteria against which digital health technologies can be assessed.

The framework has 3 components:

- Evidence for effectiveness standards, based on the functional classification of the digital health technology for its intended use(s).
- Evidence for economic impact standards.

- Supporting resources, including case studies.

The framework is not designed to describe an evaluation process for digital health technologies; evidence will still need to be critically appraised on an individual technology basis.

The evidence standards framework is not intended to assess the safety of digital health technologies, which is the responsibility of other frameworks such as the Medical Device Directive, Medical Device Regulations or the NHS digital clinical safety regulations (see the NHS information standards DCB0129 and DCB0160).

Who will use the framework?

The framework has been designed with a range of intended users in mind, specifically:

- Technology developers, including commercial organisations of any size, when considering the appropriate evidence-generation plan for a digital health technology.
- Research funders and investors who are considering funding the development of digital health technologies.
- Evaluators and others, including commissioners.

What does the framework not cover?

The evidence standards framework is not suitable for all digital health technologies.

Because the framework has been designed for digital health technologies that are commissioned in the UK health and social care system, it is less relevant to those that are downloaded or purchased directly by users (such as through app stores). The framework's relevance for technologies that are available free of charge to users will vary depending on the business model of the technology.

The framework can be used with digital health technologies that incorporate artificial intelligence (AI) using fixed algorithms. However, it is not designed for use with digital health technologies that incorporate AI using adaptive algorithms (that is, algorithms that continually change).

Does the evidence standards framework replace other existing guidance, standards or regulations?

The evidence standards framework is designed to complement existing guidance, standards and

regulations on using digital health technologies, including but not limited to:

- The Department of Health and Social Care's guide to good practice for digital and data-driven health technologies.
- The 2002 UK Medical Device Regulation (the UK implementation of the 1993 EU Medical Device Directive). From 1 January 2021, all digital technologies classed as medical devices must meet the relevant requirements of the regulation and have a UK Conformity Assessed (UKCA) mark in place before they can be used in the NHS in England, Scotland or Wales, with CE marks being recognised until 30 June 2023. In Northern Ireland, the 2017 EU Medical Device Regulations will apply. The Medicines and Healthcare Products Regulatory Agency (MHRA) medical devices flowchart helps developers of digital health technologies understand if their technology is considered a medical device under the 2002 UK Medical Device Regulation. The International Medical Device Regulators Forum has guidance on clinically evaluating software as a medical device.
- The Care Quality Commission regulation of digital healthcare providers in primary care.
- NHS Digital information standards on clinical risk management in health IT systems (see NHS information standards DCB0129 and DCB0160).
- NHSX's Digital Technology Assessment Criteria (DTAC).
- Information governance requirements that are specific to each trust or local authority, which may include completing data protection impact assessments for each technology being commissioned.
- Public Health England's resources for evaluating digital health products.
- Local information governance processes, such as within individual NHS trusts.
- Guidance from professional bodies on using digital health technologies.

How does the evidence standards framework define risk?

Risk to users

Functional classification (as described in section A of the framework) allows digital health technologies to be stratified into 3 tiers by their potential risk to users. Users are patients, carers and people in the wider health and social care system who may benefit from the technology.

In this context, risk is defined as the chance of harm coming to the user from using the digital health technology. This could include:

- Consequences for the user's health and wellbeing if the technology does not work as intended.
- Consequences for the user's health and wellbeing if the care provided by technology is not of good quality.

Economic risk

The evidence for economic impact standards (section B of the framework) describe the levels of economic analysis that should be done for digital health technologies that present different levels of economic risk.

In this context, risk is defined as a chance of harm coming to the commissioning organisation from the digital health technology, specifically any harm associated with the expected cost and system impact of commissioning such a technology. This could include:

- Commissioning a technology that has a high initial cost in relation to the available budget.
- Commissioning a technology that needs services to be redesigned, and which would affect staffing, training or associated facilities.

Functional classification

How does functional classification work for technologies with more than 1 function?

Some digital health technologies may fit into more than 1 functional classification.

For these technologies, the highest risk function should be used to define its functional classification. For example, a digital health technology may provide both information on and treatment for a condition. Of these 2 functions, providing treatment is the highest risk. So this technology would be classed as a tier C: interventions digital health technology.

Some digital health technologies have various levels of functionality depending on the level of service that is commissioned.

For these technologies, the highest risk function that is being considered for commissioning should be used to define its functional classification. For example, a digital health technology that provides health information, self-management tools and active monitoring could be classed as tier B: understanding and communicating (inform), tier C: interventions (self-manage) or tier C: interventions (active monitoring), depending on what level of service is being commissioned.

How can a technology be assessed if its functionality changes over time?

The rapid development of digital health technologies means that their functional classification may change over time.

If a digital health technology's functionality changes significantly, its functional classification may also need to be changed (so different evidence standards may apply).

How does functional classification work for technologies that are used with other digital or medical devices?

Many digital health technologies work in combination with other hardware or software.

If a digital health technology is used with otherwise standard medical or diagnostic devices, the evidence standards framework should be used only to assess the digital health technology itself.

If the digital health technology is an integral part of the product, the highest risk function of any digital component (such as apps, standalone software and online platforms) should be used to define the functional classification. Any other relevant regulations still apply to the digital health technology, hardware and any other software components. These may include regulations such as UK Conformity Assessed (UKCA) or CE marking of medical devices or NHS clinical safety standards.

What about data privacy and confidentiality?

The requirements in these areas are within the scope of NHSX's Digital Technology Assessment Criteria (DTAC).

What about health and fitness trackers and other similar apps?

The evidence standards framework has been developed to be used for digital health technologies that are being considered for commissioning in the UK health and social care system. This includes health and fitness trackers and other similar apps if they are commissioned for use by people with specific health and social care needs.

However, the framework has the potential to be used more widely. For example, the framework could be applied to health and fitness trackers and other similar apps intended to be used by the wider public and which are offered for direct download or purchase.

How should I develop evidence for my digital health technology?

Public Health England's resources for evaluating digital health products can help technology developers evaluate their products. This could include digital services, campaigns and other interventions. This guidance is aligned with the NICE evidence standards framework for digital health technologies.

NICE's Scientific advice service has developed the Medtech Early Technical Assessment (META) Tool to help medical technology companies plan their evidence generation.

The META Tool is an online service that helps medical technology developers optimise development plans for their medical technology. It provides a structured framework. It can help with identifying potential gaps in product development plans and the potential next steps to bring a product to market.

The META Tool helps companies understand what level of evidence is needed to show their product will be valuable to the NHS. It can be used at any stage of product development.

It was developed by NICE in collaboration with Greater Manchester Academic Health Science Network (AHSN), with their delivery partner TRUSTECH, and is also available through other relevant organisations under licence.

How can I tell NICE about my digital health technology?

Companies who wish to contact NICE about their digital health technology can use HealthTech Connect.

HealthTech Connect is a secure online system for identifying and supporting health technologies as they move from inception to adoption in the UK health and care system. It is intended for devices, diagnostic and digital health technologies that either:

- offer measurable benefits to patients (or other health and care service users) compared to those already offered by current routine practice in the UK, or
- provide measurable benefits to the UK health and care system compared to those already offered by current routine practice in the UK.

It is not intended to be a catalogue of all available health technologies. It was developed by NICE with funding from NHS England. A range of partner organisations helped to develop the system including industry associations:

- NHS Supply Chain
- Health Technology Wales
- Healthcare Improvement Scotland
- Department for International Trade
- Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care (AXREM)
- Association of British HealthTech Industries (ABHI)
- British In Vitro Diagnostics Association (BIVDA)
- The Academic Health Science Network (AHSN) Network
- National Institute for Health Research (NIHR)
- Life Sciences Hub Wales

- Welsh Health Specialised Services Team.

HealthTech Connect aims to reduce the duplication and complexity involved in adopting a health technology in the UK. It is a clear and simple point of entry for health technologies to access support and national evaluation programmes.

How was the framework developed?

In developing this framework, NICE reviewed existing frameworks for categorising and assessing digital health technologies, as well as the published literature on digital health technology evaluation systems.

Between June 2018 and January 2019, the following stakeholders provided comments and feedback:

- industry representatives and developers
- healthcare commissioners
- academic experts in health technology assessment and digital health technologies
- clinical experts with special interests in digital health technologies
- organisations responsible for promoting innovations such as AHSNs and Digital Accelerators.

The standards were subject to a targeted consultation with relevant stakeholders.

NICE plans to publish details separately on how the evidence standards were developed. Selected studies and other publications used in developing this work include:

- Murray E, Hekler EB, Andersson G et al. (2016) Evaluating digital health interventions: key questions and approaches. American Journal of Preventative Medicine 51(5):843–51
- Nielsen SL and Rimpiläinen S (2018) Report on International Practice on Digital Apps
- Baumel A, Birnbaum ML, Sucala M (2017) A systematic review and taxonomy of published quality criteria related to the evaluation of user-facing eHealth programs. Journal of Medical Systems 41(8):128
- Grundy QH, Wang Z, Bero LA (2016) Challenges in assessing mobile health app quality: a systematic review of prevalent and innovative methods. American Journal of Preventative Medicine 51(6):1051–9
- Consard Limited, Ruck A, Wagner Bondorf S, Lowe C (2016) Second draft of guidelines: EU guidelines on assessment of the reliability of mobile health applications [PDF]

- Lewis TL, Wyatt JC (2014) mHealth and mobile medical Apps: a framework to assess risk and promote safer use. Journal of Medical Internet Research 16(9):e210
- Khoja S, Durrani H, Scott RE et al. (2013) Conceptual framework for development of comprehensive e-health evaluation tool. Telemedicine and e-Health 19(1):48–53
- World Health Organization (2018) Classification of digital health interventions v1.0 – A shared language to describe the uses of digital technology for health
- US Food and Drug Administration (2017) Software as a Medical Device (SaMD): clinical evaluation guidance for industry and Food and Drug Administration staff
- Medicines and Healthcare products Regulatory Agency (2015) Medical devices: conformity assessment and the CE mark
- McNamee P, Murray E, Kelly MP et al. (2016) Designing and undertaking a health economics study of digital health interventions. American Journal of Preventative Medicine 51(5):852–60
- Husereau D, Drummond M, Petrou S et al. (2013) Consolidated Heath Economic Evaluation Reporting Standards (CHEERS) – explanation and elaboration: a report of the ISPOR Health Economic Evaluations Publication Guidelines Good Reporting Practices Task Force. Value in Health 16(2):231–50
- European Network for Health Technology Assessment (2015) Methods for health economic evaluations – a guideline based on current practices in Europe [PDF]
- Michie S, Yardley L, West R et al. (2017) Developing and evaluating digital interventions to promote behavior change in health and health care. Journal of Medical Internet Research 19(6):e232

What priorities were identified for future development of the evidence standards framework?

NICE published the first version of the evidence standards framework in December 2018. Based on stakeholder comments and feedback received in early 2019, we made changes to the framework. These changes were mainly additional clarifications and further explanation of the evidence standards.

In October 2019 we launched a second stakeholder survey and did interviews to find out people's experiences of using the evidence standards framework. More information about the results of the survey can be found in the feedback report.

The digital healthcare environment is rapidly evolving and we aim to regularly review and update the evidence standards framework, so that it reflects developments in areas such as regulation and standards for use of digital health technologies in the UK health and social care system.

Glossary

Artificial intelligence (AI)

AI is an area of computer science that makes it possible for machines to learn from new experiences, adjust outputs and perform human-like tasks. It is generally classified into:

- Narrow AI, which focuses on a specific task, or works within a narrow set of parameters such as reading radiology scans or optimising hospital workflows.
- Strong or general AI, which refers to AI that can learn to do several different tasks.

AI can incorporate algorithms that do not automatically change over time (fixed algorithms) or algorithms that are automatically and continually updated (adaptive algorithms).

Definition from The AHSN Network Accelerating Artificial Intelligence in health and care: results from a state of the nation survey.

Digital Technology Assessment Criteria (DTAC)

The DTAC has been designed by NHSX to include baseline assessment criteria that validate the suitability and function of digital health technologies for use by the NHS, social care staff or directly by citizens. The assessment criteria are focused on 5 core areas: clinical safety; data protection; technical assurance; interoperability; usability and accessibility. DTAC replaces the existing Digital Assessment Questionnaire (DAQ) and Digital Assessment Portal (DAP). Further information can be found in NHSX webpages describing the assessment of digital health services.

Economic analysis

Study or analysis of the cost of using and distributing health or social care resources.

Real-world data (RWD)

An umbrella term for data on the effects of health interventions (for example, safety, effectiveness, resource use, etc) that are not collected in the context of highly-controlled randomised controlled trials. Instead, RWD can either be primary research data collected in a manner that reflects how interventions would be used in routine clinical practice, or secondary research data derived from

routinely collected data. Data collected include, but are not limited to, clinical and economic outcomes, patient-reported outcomes and health-related quality of life. RWD can be obtained from many sources including patient registries, electronic medical records, and claims databases.

Definition from imi GetReal glossary.

Real-world evidence

The evidence derived from the analysis and/or synthesis of RWD.

Definition from imi GetReal glossary.

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