NICE National Institute for Health and Care Excellence

Evidence standards framework for digital health technologies

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Contents

Introduction

The NICE evidence standards framework (ESF) for digital health technologies (DHTs) describes standards for the evidence that should be available or developed for DHTs to demonstrate their value in the UK health and social care system. The ESF encompasses evidence of performance relevant to the purpose of the technology and evidence of economic impact relative to the financial risk. The ESF has been updated in 2022 to also include associated design factors and deployment considerations.

The ESF can be used by evaluators and innovation teams in the NHS and care system when they are evaluating a DHT for a commissioning or purchasing decision. This will enable high-quality innovation to be identified and used in the UK. The ESF is not mandated, so it is not compulsory for the ESF to be used in commissioning DHTs.

The ESF can also be used by DHT companies to understand how the UK health and care system evaluates DHTs, and what kinds of evidence should be shown to facilitate commissioning or purchasing decisions in the NHS and care system.

The ESF has been designed to complement the existing regulatory and technical standards that apply to DHTs. The ESF focuses on evaluating DHTs to ensure they are likely to perform as expected and represent good value for money to the health and care system. The standards to demonstrate evidence for performance have been set at levels that are intended to be realistic and achievable for DHT companies, while being of a sufficiently high standard to give the health and social care system confidence in the DHT. This balance is intended to encourage the confident use of innovative, effective DHTs in the health and social care system. The standards on delivering value are based on the guidance evaluation methods used at NICE, and are designed to assess the likely economic impact of a DHT. We have designed the ESF within the context of a health and social care system that is seeking innovative ways to improve care while reducing cost burden on the system.

The development of the medical device regulatory framework and evaluation methods for DHTs, particularly those with adaptive algorithms, is progressing rapidly and we expect that the ESF will be updated to reflect the changes in the health technology assessment landscape for these technologies. We anticipate that the ESF will be reviewed annually to ensure that it remains up to date with other regulatory and assurance guidance. We expect the next update to the ESF to follow the Medicines and Healthcare products Regulatory

Agency (MHRA) implementation of the Software and AI as a Medical Device Change Programme.

NICE is grateful to the wide range of stakeholders who helped develop the concepts and content, and to all those who have provided feedback on the ESF since it first published in December 2018.

Find out more details about the development and use of the ESF in the ESF user guide.

The ESF is presented here in 4 sections:

- Section A: Technologies suitable for evaluation using the ESF
- Section B: Classification of DHTs
- Section C: Evidence standards tables
- Section D: Early deployment standards for evidence-generation programmes.

Section A: Technologies suitable for evaluation using the evidence standards framework

The NICE evidence standards framework (ESF) has been designed to be suitable for the evaluation of most digital health technologies (DHTs) that are likely to be commissioned in the UK health and social care system.

DHTs are digital products intended to benefit people or the wider health and social care system. This may include:

- smartphone apps
- standalone software
- online tools for treating or diagnosing conditions, preventing ill health, or for improving system efficiencies
- programmes that can be used to analyse data from medical devices such as scanners, sensors or monitors.

The ESF is not intended to be used for evaluating the following types of DHT:

- software that is integral to, or embedded in, a medical device or in vitro diagnostic (IVD), also called software in a medical device (SiMD)
- DHTs designed for providing training to health or care professionals (such as virtual reality [VR] or augmented reality [AR] surgical training)
- DHTs that facilitate data collection in research studies.

The ESF can be used to evaluate all DHTs commissioned in the health and care system for medical, health or wellness, or system efficiency purposes. It is applicable to medical therapeutic and diagnostic technologies including IVDs and screening technologies. The ESF can be used for technologies where the intended benefit is at the population level as well as those that benefit the individual service user or the health and care system.

The ESF is intended to be used alongside requirements for regulation and does not

constitute or replace any regulatory process. The accompanying user guide describes how the ESF fits alongside other regulatory and quality assurance measures for digital healthcare in the NHS and care system. It can be used to evaluate DHTs that are regulated as medical devices or IVDs in the UK.

The ESF has been updated in 2022 to include standards relevant to DHTs whose performance is expected to change over time (such as those with machine-learning algorithms that are expected to retrain over time).

Section B: Classification of digital health technologies

Classifying digital health technologies (DHTs) by intended purpose (see figure 1) allows them to be stratified into tiers based on the potential risk to service users and to the system. The evidence level needed for each tier is proportionate to the potential risk to service users from the DHTs in that tier. The classification used in the evidence standards framework (ESF) has been designed so that most regulated medical devices and in vitro diagnostics (IVDs) will be in tier C. Table 1 describes each classification group in more detail and gives some examples. Specific examples of DHTs classified using the ESF classification system are in the ESF classification examples.

DHTs in tier C are divided into 4 classification groups to align with the software as a medical device (SaMD) classification framework proposed by the International Medical Device Regulators Forum (IMDRF). The IMDRF classification framework is based on 2 aspects of the technology: the significance of information and the state of the healthcare situation or condition. The tier C groups of the ESF reflect the significance of information part of the IMDRF framework and the impact of the healthcare situation or condition is captured in the evidence standards. IVDs are excluded from the IMDRF, but in the ESF classification, we would expect most IVDs to fall within tier C.

Table 2 is adapted from the IMDRF classification document showing the relationship between the ESF classification groups and the likely medical device classes. Medical device classifications may also consider other factors such as whether the user is a healthcare professional or not and whether calculations are easy to verify. The Medicines and Healthcare products Regulatory Agency (MHRA) consultation on the future regulation of medical devices in the UK contains a section on software as a medical device.

For more information about how to use the classification and how it was developed, please see the ESF user guide.

Figure 1 DHTs classified by intended purpose and stratified into risk tiers

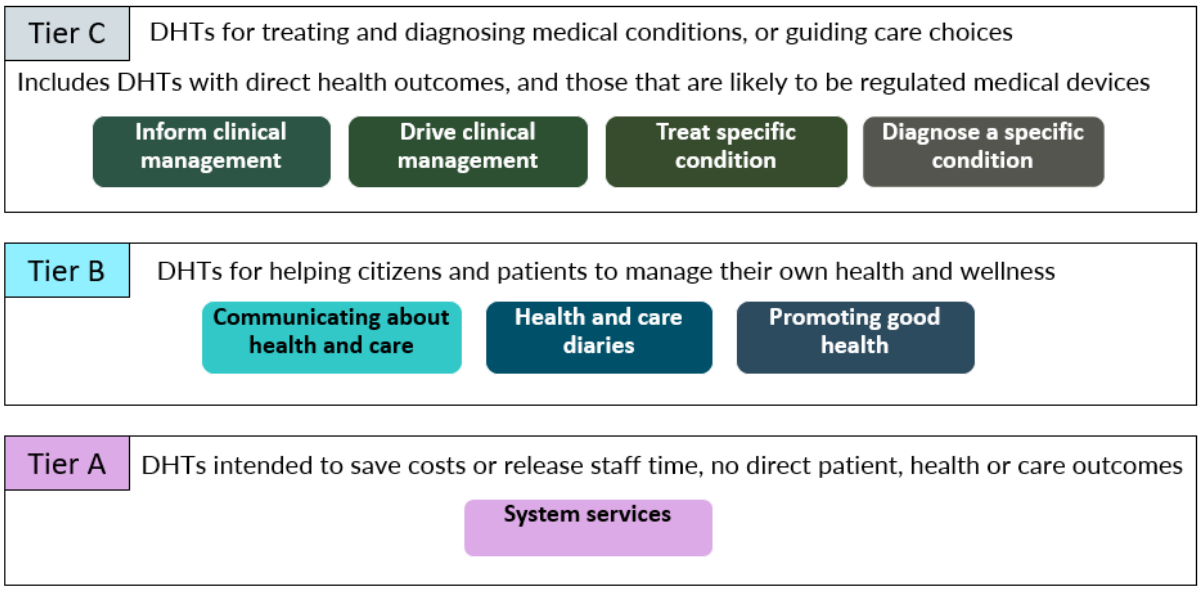


Table 1 ESF evidence tiers and classification groups

Tier and group	Description	This tier includes (for example)	This tier excludes (for example)
Tier A: **System service** DHTs intended to release costs or staff time, or to improve efficiency.	Unlikely to have direct health outcomes measurable for individual service users.	Electronic prescribing systems that do not provide patient-level advice on prescribing, nor highlight any contraindications. Triaging systems that do not affect care decisions or access to care, such as those that manage non-clinical staffing or resources.	DHTs that influence treatment or diagnoses, such as early warning systems that monitor vital signs. Triaging systems that use individual patient health data (such as vital signs, symptoms or self-reported health measures) to guide treatment, diagnosis or care decisions.

Tier and group	Description	This tier includes (for example)	This tier excludes (for example)
Tier B: **Communicating about health and care** Communicating with health and care professionals or others, to help service users to manage their health and care.	Allows 2-way communication between service users and professionals, carers, third-party organisations or peers.	Instant messaging apps for health and social care. DHTs that provide platforms for communication with carers or professionals or other service users.	DHTs that provide clinical content themselves (such as cognitive behavioural programmes for depression).
Tier B: **Health and care diaries** Health and care diaries to help service users to manage their own health and wellness.	Allows service users to record information to create health diaries. Information and data stay with the service user and are not automatically shared with others for review.	Health tracking information, such as from fitness wearables. Symptom or mood diaries.	DHTs that automatically share data or information with professionals, carers or other service users in order to inform care decisions. DHTs that provide treatment for or diagnosis of a condition.

Tier and group	Description	This tier includes (for example)	This tier excludes (for example)
Tier B: **Promoting good health** Population-level information to help people and service users to maintain healthy lifestyles and manage conditions.	Provides non-personalised information and resources to service users. May encourage behaviours that promote good health and address issues such as smoking, eating and exercise. May also provide information about specific conditions.	DHTs used as part of general weight-loss programmes. DHTs that aid good sleep habits.	DHTs that describe themselves as a treatment for a diagnosed condition.

Tier and group	Description	This tier includes (for example)	This tier excludes (for example)
Tier C: **Inform clinical management**	DHTs that record and calculate data and transmit the data to a professional, carer or third-party organisation, to inform clinical management decisions in the future. Also, DHTs that provide personalised information or guidance to end users to promote healthy living. Information provided by the DHT will not trigger an immediate or near-term action by clinical or care staff.	DHT that records and transmits historical blood pressure information for a healthcare provider's later review. DHTs that provide personalised information or guidance using behaviour change techniques, to promote good health and healthy lifestyles. Symptom monitors where data is automatically shared with care teams for later review. May include simple calculators (may not be in remit for regulation as medical devices) as well as complex calculators (more likely to be in	DHTs whose intended purpose is a treatment for a diagnosed condition. DHTs that monitor a condition to trigger immediate or near-term action. DHTs that offer population-level information or guidance.

Tier and group	Description	This tier includes (for example)	This tier excludes (for example)
		remit for regulation).	
Tier C:	Information provided by the DHT will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition, or will be used to guide next diagnostics or next treatment interventions.	DHT that analyses heart rate data intended for a clinician as an aid in diagnosing arrhythmia. Triaging systems that use individual patient health data, or which impact on care decisions or access to care. Prediction tools such as software to assess risk of developing a condition, likelihood of disease progression or response to a treatment.	DHTs that describe themselves as a treatment for a diagnosed condition. DHTs that provide information that triggers immediate or near-term action. Triaging systems that do not impact on care decisions or access to care.
Tier C:	Information provided by the DHT will be used to take an immediate or near-term action to diagnose, screen or detect a disease or condition.	DHT that performs diagnostic image analysis for making treatment decisions in service users with acute stroke.	DHT offering general (non-personalised) health or wellness advice.

Tier and group	Description	This tier includes (for example)	This tier excludes (for example)
Tier C:	Information provided by the DHT will be used to take an immediate or near-term action to treat, prevent or mitigate by means of providing therapy to a human body.	DHT that uses the microphone of a smart device to detect interrupted breathing during sleep and sounds a tone to rouse the sleeper.	DHT offering general (non-personalised) health or wellness advice.

Table abbreviations: DHT, digital health technology; ESF, evidence standards framework.

Table 2 Potential mapping between the ESF classification groups in tier C and the medical devices classes

ESF classification group in tier C	Description adapted from IMDRF	Healthcare situation or condition with the medical device class as per IMDRF categories mapped to the current UK medical device regulations
Inform clinical management	DHTs that record, calculate and transmit data to a professional, carer or third-party organisation to inform clinical management in the future. Informing clinical management infers that the information provided by the SaMD will not trigger an immediate or near-term action: • To inform of options for treating, diagnosing, preventing or mitigating a disease or condition. • To provide clinical information by aggregating relevant information (for example, disease, condition, drugs, medical devices and population).	• Non-serious: Class 1 • Serious: Class 1 • Critical: Class 2a

ESF classification group in tier C	Description adapted from IMDRF	Healthcare situation or condition with the medical device class as per IMDRF categories mapped to the current UK medical device regulations
Drive clinical management	Information provided by the DHT will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition, and will be used to guide next diagnostics or next treatment interventions. Driving clinical management infers that the information provided by the SaMD will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition, and will be used to guide next diagnostics or next treatment interventions: • To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device. • To aid in diagnosis by analysing relevant information to help predict risk of a disease or condition or as an aid to making a definitive diagnosis. • To triage or identify early signs of a disease or conditions.	• Non-serious: Class 1 • Serious: Class 2a • Critical: Class 2b
Diagnose a condition	Information provided by the DHT will be used to take an immediate or near-term action to diagnose, screen or detect a disease or condition.	• Non-serious: Class 2a • Serious: Class 2b • Critical: Class 3

ESF classification group in tier C	Description adapted from IMDRF	Healthcare situation or condition with the medical device class as per IMDRF categories mapped to the current UK medical device regulations
Treat a condition	Information provided by the DHT will be used to take an immediate or near-term action to treat, prevent or mitigate by means of providing therapy to a human body.	• Non-serious: Class 2a • Serious: Class 2b • Critical: Class 3

Table abbreviations: DHT, digital health technology; ESF, evidence standards framework; IMDRF, International Medical Device Regulators Forum; SaMD, software as a medical device.

This table has been adapted from the table in section 7.2 of the IMDRF document Software as a Medical Device. The medical device class names included here align with the classes currently used by the MHRA (low risk: Class 1; high risk: Class 3). IVDs are excluded from the IMDRF and so are not included in this table. The medical device class may also be influenced by other factors including the user type (patient or professional) and level of professional oversight. This table will be reviewed and updated in line with changes to MHRA regulations.

Section C: Evidence standards tables

The NICE evidence standards framework (ESF) has been designed to inform the evaluation of digital health technologies (DHTs) for use in the NHS and social care system. The standards are presented in groups related to phases of the DHT product life cycle. There are 21 standards arranged in 5 groups:

- **Design factors:** The 9 standards identify key aspects of the design process that impact the DHT's value to the health and care system, including ensuring the technology has the appropriate technical standards for safety and reliability. Standards 1 to 6 apply to tier A, B and C DHTs. Standards 7 to 9 do not apply to tier A DHTs.
- **Describing value:** The 4 standards apply across all tiers and provide information to build the value proposition of the DHT. Standards 10 to 13 apply to tier A, B and C DHTs.
- **Demonstrating performance:** Standards 14 to 16 are designed to help ensure that the DHT meets its performance expectations. Standard 14 only applies to tier C DHTs. Standards 15 and 16 apply to tier A, B and C DHTs.
- **Delivering value:** The 2 standards apply to DHTs in all tiers and show how DHTs should demonstrate their value for money.
- **Deployment considerations:** The 3 standards help to ensure that the claimed benefits of the DHT can be realised in practice, and apply to all 3 tiers.

Figure 2 The 5 groups of evidence standards relating to different aspects of the product life cycle

Summary of NICE ESF standards

Tables 3 to 7 summarise the 21 standards and specify the classification tiers to which each standard applies. Additional information is provided in the section on how to meet the standards, to explain the kind of information that a company needs to show in order for a DHT to meet each standard.

Table 3 Design factors

Standard	Tiers to which the evidence standard applies
1: the DHT should comply with relevant safety and quality standards	A, B and C
2: incorporate intended user group acceptability in the design of the DHT	A, B and C
3: consider environmental sustainability	A, B and C
4: consider health and care inequalities and bias mitigation	A, B and C
5: embed good data practices in the design of the DHT	A, B and C
6: define the level of professional oversight	A, B and C
7: show processes for creating reliable health information	B and C
8: show that the DHT is credible with UK professionals	B and C
9: provide safeguarding assurances for DHTs where users are considered to be in vulnerable groups, or where peer-to-peer interaction is enabled	B and C

Table abbreviation: DHT, digital health technology.

Table 4 Describing value

Standard	DHTs it applies in
10: describe the intended purpose and target population	A, B and C
11: describe the current pathway or system process	A, B and C

Standard	DHTs it applies in
12: describe the proposed pathway or system process using the DHT	A, B and C
13: describe the expected health, cost and resource impacts compared with standard or current care or system processes	A, B and C

Table abbreviation: DHT, digital health technology.

Table 5 Demonstrating performance

Standard	DHTs it applies in
14: provide evidence of the DHT's effectiveness to support its claimed benefits	C
15: show real-world evidence that the claimed benefits can be realised in practice	A, B and C
16: the company and evaluator should agree a plan for measuring usage and changes in the DHT's performance over time	A, B and C

Table abbreviation: DHT, digital health technology.

Table 6 Delivering value

Standard	DHTs it applies in
17: provide a budget impact analysis	A, B and C
18: for DHTs with higher financial risk, provide a cost-effectiveness analysis	A, B and C

Table abbreviation: DHT, digital health technology.

Table 7 Deployment considerations

Standard	DHTs it applies in
19: ensure transparency about requirements for deployment	A, B and C
20: describe strategies for communication, consent and training processes to allow the DHT to be understood by end users	A, B and C

Standard	DHTs it applies in
21: ensure appropriate scalability	A, B and C

Table abbreviation: DHT, digital health technology.

Terms used in the evidence standards framework

This section defines terms that have been used in the evidence standards framework (ESF). Additional definitions are provided in the accompanying ESF user guide.

Company

Any commercial entity that is planning to sell or selling a digital health technology (DHT) to a healthcare provider. The company may be the same as the developer who created the DHT or it may be another organisation who is trying to promote the use of the technology in the health and care system.

Data driven

A data-driven DHT is a DHT that meets any of the following descriptions:

- It contains algorithms that were trained using patient data or datasets. These algorithms could be adaptive, meaning they change over time, or fixed.
- It uses decision thresholds or cut-off values (such as for diagnosing a condition or triaging patients for different treatments) that were created using patient data or datasets.

End user

Any person whose is operating the DHT. For software as a medical device or imaging software, this is likely to be the healthcare professional. For health and wellbeing apps, this is likely to be the service user.

Evaluator

Any person or group of people who judges the quality or value of a DHT based on information and evidence provided. These could include NHS commissioners, buyers of

DHTs and local evaluators.

Intended purpose

The intended purpose is the objective intent of the manufacturer regarding the use of a DHT. It should state the indication and target population, including when, how and by whom the DHT should be used. The intended purpose of the DHT should be reflected in the information provided by the manufacturer but also needs to take into account how the technology is likely to be generally used. Use outside of an intended purpose may impact the performance and safety of the device. For technologies which fall under the medical device regulations, the intended purpose should allow consistent determination of the regulatory medical device classification and facilitate the development of an adequate risk management, clinical evaluation, quality management and post-market surveillance system.

Service user

Any person whose health and care is being affected by the use of a DHT.

How to meet the standards

Design factors

Standard 1: the digital health technology (DHT) should comply with relevant safety and quality standards

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 1

Companies should demonstrate that all safety and quality standards relevant to their DHT have been met.

Examples of standards that may apply to different DHTs include:

- UKCA marking as a medical device or in vitro diagnostic (IVD) under the UK regulations (Medicines and Healthcare products Regulatory Agency [MHRA] provides guidance on medical devices: software applications [apps]) or CE marking (until June 2023).
- Regulation by the Care Quality Commission (CQC) for digital health services in England, Care Inspectorate Wales or Care Inspectorate Scotland.
- Following regulations outlined in the Data Protection Act 2018, the UK's implementation of the General Data Protection Regulation (GDPR).
- Registration with the Information Commissioner's Office as a data processor.
- For use in the NHS, DHTs may need to show compliance with the Digital Technology Assessment Criteria (DTAC), which includes DCB0129 and DCB0160, NHS Digital's data security and protection toolkit and interoperability toolkit, and NHS service standard.
- Local information governance requirements including data protection impact assessments.

- Other non-mandated standards include: ISO 13485 for quality management systems, ISO 11073 for personal health data, IEC 82304-1 for safety and security for health software, ISO 14155 on clinical investigations for medical devices, ISO/TR 20416 on post-market surveillance for medical devices, BS EN ISO 14971 application of risk management to medical devices, and BS EN 62304 medical device software – software life cycle processes.

Standard 2: incorporate intended user group acceptability in the design of the DHT

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 2

Describe how representatives from intended user groups were involved in the design, development or testing of the DHT. Depending on who is intended to operate the DHT, the intended users may include patient groups and service users, or health and care professionals. Describe how user acceptability was appraised and provide any available data to show user acceptability with the DHT.

Section D1 of the NHS DTAC also refers to usability and accessibility. DHTs that have evidence of meeting ISO's standard IEC 62366-1, application of usability engineering to medical devices, may be considered to have already demonstrated compliance with this standard.

Standard 3: consider environmental sustainability

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 3

The NHS has set ambitions to have a net zero carbon footprint by 2040. Environmental sustainability should be factored into all stages of the life cycle of the DHT starting at the design of the DHT. The company should provide a narrative description of any expected environmental sustainability benefits and negative impacts from using the DHT. This should focus on impacts on greenhouse gas emissions, in line with the NHS carbon footprint and carbon footprint plus.

Standard 4: consider health and care inequalities and bias mitigation

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 4

Health inequalities considerations should be factored into the design of the DHT. Describe how this has been approached and how this has been included in the design of the DHT. Describe any specific positive impacts and any efforts to reduce negative impacts on health inequalities.

If the DHT has a claim of addressing a health or care inequality, it should also show evidence that the DHT contributes to:

- challenging health inequalities in the UK health and social care system, or improving access to care among hard-to-reach populations
- promoting equality, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (as described in the Equalities Act 2010) and others.

For early deployment (ED) DHTs being used in evidence-generation programmes, plans for collecting evidence to support the health inequalities claims should be provided.

NHS Digital's guide on digital inclusion for health and social care provides information for companies and providers to understand digital inclusion and steps that can be taken to evaluate and support digital inclusion. The Open Data Institute's Data Ethics Canvas is a tool that can be used to identify and manage ethical issues in projects that use data. This includes exploring the impacts of the project on different people and identifying sources of bias.

For data-driven DHTs (including those with artificial intelligence), the company should describe any actions taken in the design of the DHT to mitigate against algorithmic bias that could lead to unequal impacts between different groups of service users or people.

Standard 5: embed good data practices in the design of the DHT

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 5

Good data practices are essential to creating high-quality data-driven DHTs. Any datasets used to train, validate or develop the DHT should be of a high quality. One indicator of quality is that the following information can be provided by the company:

- which datasets (title, source, version) were used for training and validating the DHT
- the size of the training and validation datasets
- how the data was labelled and 'ground-truth' established
- why these datasets were collected, and by what means (manual input, through monitors or other devices)
- diversity (demographics, age, clinically relevant subgroups) in these datasets used and how this reflects the intended target population for the DHT
- any synthetic training or validation data should be highlighted; synthetic data should be supported by real data on how any decision thresholds have been set and how these align to current care.

For DHTs that incorporate machine learning, companies should follow the MHRA guiding principles on good machine learning practice for medical device development.

Standard 6: define the level of professional oversight

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 6

During the design of the DHT, the company should define the anticipated level of professional oversight needed when the DHT is used in practice. This must be clearly described. The level of professional oversight should be acceptable to relevant health and care professionals. Professional oversight may include (among others):

- expert review of each decision or output on a case-by-case basis
- periodic overarching review of the trends in the decision outputs of the DHT, to ensure that the decisions are aligned to, or calibrated against, best practice

- monitoring for occasions where the DHT's decision output has been overridden by professionals.

The level of professional oversight should be proportionate to the level of risk associated with failure of the DHT to perform as expected. Higher levels of professional oversight may be needed when the consequences of the DHT's failure are serious or critical.

Standard 7: show processes for creating reliable health information

Applies to DHTs in tiers B and C.

Information that can be used to meet standard 7

Health information is text, video or other educational material for people, patients or healthcare professionals, to help them to better understand their health and care. This could include information about conditions, tests or treatments. The developer should be able to show that processes are in place to maintain any health information provided by the DHT, which are:

- valid (aligned to best available sources, such as NICE guidance, relevant professional organisations or recognised UK patient organisations, and appropriate for the target population)
- accurate
- reviewed and updated by relevant experts (such as health and care professionals in the relevant field) at defined intervals, such as every year
- sufficiently comprehensive.

Standard 8: show that the DHT is credible with UK professionals

Applies to DHTs in tiers B and C.

Information that can be used to meet standard 8

Show that relevant health or care professional(s) working in the UK health and social care system have either been involved in designing, developing or testing the DHT, or given

their support to the UK deployment of the DHT.

Be able to show that the DHT is viewed as useful and relevant by professional experts or expert groups in the relevant field. This could include providing evidence to support key factors such as the choice of behaviour change techniques used in the DHT.

Standard 9: provide safeguarding assurances for DHTs where users are considered to be in vulnerable groups, or where peer-to-peer interaction is enabled

Only applies to DHTs in tiers B and C, if the DHT is intended to be used by people in vulnerable groups, such as children or at-risk adults, or where peer-to-peer interaction is enabled through the DHT. NHS England defines an at-risk adult as an adult 'who may be in need of community care services by reason of mental or other disability, age or illness; and who is or may be unable to take care of him or herself, or unable to protect him or herself against significant harm or exploitation'.

Information that can be used to meet standard 9

Show that appropriate safeguarding measures are in place around peer support and other communication functions enabled through the DHT:

- Describe who has access to the platform and their roles within the platform.
- Describe why these people or groups are suitable and qualified to have access.
- Describe any measures in place to ensure safety for vulnerable users and in peer-to-peer communication, for example, through user agreements or moderation.

Describing value

Standard 10: describe the intended purpose and target population

Applies to DHTs in tiers A, B and C.

Describe the target population and intended purpose for the DHT. Include any inclusion and exclusion criteria that apply.

Describe the expected uptake profile of the DHT.

Information that can be used to meet standard 10

The target population for tier C DHTs is likely to be defined by a particular health condition and position in the care pathway. For regulated medical devices, the intended population for the DHT will be defined in the information associated with the device, and the target population can match this. For tier B DHTs, the target population is the group of people who are intended to benefit from using the DHT. For tier A DHTs, the target population is the group that benefits from using the DHT; which could be service users, clinical staff or administrative staff. Any important subgroups should also be identified.

The size of the target population should be calculated using appropriate and current national or local sources (for example, accurate epidemiological data of prevalence and incidence of the relevant health problem), or expert estimates if this is not available. Note that NICE's resource impact assessment manual describes an approach to calculating population size.

The expected uptake profile describes the proportion of people within the target population who are expected to use the DHT, and their usage rates. This may be impacted by digital literacy within the intended user population, availability of necessary connectivity, and access to necessary hardware or devices.

Demonstrate that the expected uptake profile is:

- calculated using uptake rates from pilot data or other usage data from the company
- validated as an accurate representation of what is expected (including any variations by subgroup and over time) by showing agreement and support from relevant professionals in the UK health and social care system
- mindful of subgroups with different expected uptake rates and how these may change over time.

Standard 11: describe the current pathway or system process

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 11

Use national clinical guidelines, national guidance or academic literature and consultation with healthcare professionals and service users to map out the existing care pathway(s) or system processes for the intended purpose and target population (as described in standard 10).

Use a comprehensive, detailed and stepwise approach (for example, using a flow chart).

The representation of current care or system processes should be comprehensive and relevant to the intended purpose and the target population, and should be checked and validated by relevant professionals in the UK health and social care system.

If there is no existing care pathway or system process, the impact of adopting the technology should be clearly specified using an approach that can be used as a basis for a potential economic evaluation.

If there is more than 1 existing care pathway or system process, describe each of them.

Standard 12: describe the proposed pathway or system process using the DHT

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 12

Provide details of how the proposed care pathway or system process using the DHT will be different to the current pathway or system process described for standard 11, including:

- whether using the DHT would replace an existing technology or step in current care, would complement current care or whether it would be in addition to current care
- any changes that would need to be made to infrastructure, service provision and workforce, compared with current care or process
- whether the proposed pathway crosses between existing system care boundaries, such as between primary and secondary care
- changes needed to implement, operate and maintain the proposed pathway or

process using the DHT

- need for training and education for health and care professionals or end users, in order to effectively implement and use the DHT
- any influential contextual issues that may act as barriers for enablers to implementation.

Standard 13: describe the expected health, cost and resource impacts compared with current care or system processes

Applies to DHTs in tiers A, B and C. The information used to meet this standard may be used to inform the budget impact analysis in standard 17, and health economic evaluation in standard 18.

Information that can be used to meet standard 13

To assess impact of the DHT, we need to understand and compare the health and system benefits from the current pathway or process and the proposed pathway or process using the DHT:

- Describe the health benefits and other outcomes (such as system efficiency, care outcomes, or structural and procedural effects) associated with current practice. If possible, quantify the uncertainty associated with these figures (for example, with confidence intervals or probability distribution).
- Describe the anticipated health benefits and other outcomes (such as system efficiency, care outcomes, or structural and procedural effects) associated with using the DHT. If possible, quantify the uncertainty associated with these figures (for example, with confidence intervals or probability distribution).

Structural and procedural effects could include access to care, health literacy, adherence to care plans, or coordination of care.

Also, it is important to understand whether there are any expected additional costs or cost savings as well as resource impact from the DHT compared with current practice:

- Describe the costs and resource use associated with current practice. If possible, quantify the uncertainty associated with these figures (for example, with confidence

intervals or probability distribution).

- Describe the expected costs and resource use associated with using the DHT. If possible, quantify the uncertainty associated with these figures (for example, with confidence intervals or probability distribution).

The sources for this information should:

- be from the most robust evidence available, for example from clinical studies on the DHT and on current care options (if available), real-world evidence, observational studies or from expert opinion
- be the same as referred to in the performance and effectiveness standards (if these apply).

Evidence synthesis can be used if there are several studies, in which case a sensitivity analysis should be shown.

Estimates should have minimal bias and all uncertainties should be accurately characterised.

Demonstrating performance

Standard 14: provide evidence of the DHT's effectiveness to support its claimed benefits

Applies to DHTs in tier C.

Information that can be used to meet standard 14

For tier C DHTs, evidence for effectiveness must be shown.

The evidence should show that using the DHT impacts on clinical management of the relevant condition, in a setting relevant to the UK health and social care system or that it provides reliable test results that can be used to impact clinical management. Outcomes relevant to the intended purpose (value proposition) and claimed benefits of the DHT should be captured.

Choice of study design should be guided by the intended purpose (value proposition) and claimed benefits of the DHT, and comparative studies are generally more informative than non-comparative studies. Some general guidance on assessing the quality of evidence includes:

- The results of studies done in a setting that is similar to the UK health and care system (such as where the care pathway is similar, patients have similar care options, or similar kinds of staff are involved in care) are more easily generalisable to the UK system than those of studies done in settings that are very different to the UK system.
- Prospective studies are often considered to be more valuable than retrospective studies because they can be designed to capture the most relevant outcomes, and have lower risk of bias in terms of who is included in the studies.
- Studies that are published in peer-reviewed journals have usually had some independent assessment of their quality before publication.
- The studies used to support claimed benefits should be done on the DHT in question. If supporting evidence from similar DHTs is presented, then a clear rationale should be provided explaining how that evidence is generalisable.
- There are different ways to appraise the quality of research studies. Appendix H of NICE's developing NICE guidelines: the manual provides a comprehensive list of checklists that can be used to assess risk of bias or quality of different study types.
- NICE has published a framework on best practice in developing real-world evidence, which describes how real-world evidence should be assessed.

Qualitative studies can be useful for showing patient and healthcare professional views and experience of using the DHT.

If the DHT is intended to be used for situations or conditions in which accurate, timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health, the increased risk associated with the situation or condition is likely to mean that less uncertainty in the performance of the DHT is acceptable.

Additional evidence could include any well-designed studies or data in addition to those mentioned below for the 4 different functional groups in tier C. This could be real-world data, prospective or retrospective studies that can serve to reduce uncertainty about the performance of the DHT.

Effectiveness of DHTs that inform clinical management

Evidence to support the claimed benefits of the DHT can include real-world evaluations of its clinical utility, or test accuracy studies for diagnostics.

Effectiveness of DHTs that drive clinical management

The evidence should include 1 or more high-quality studies to support the claimed benefits of the DHT, done in a setting relevant to the UK health and social care system, and show improvements in relevant outcomes, such as:

- clinically relevant outcomes
- patient-relevant outcomes
- test accuracy
- time to diagnosis.

This could include any of the following study designs:

- test accuracy studies, using an appropriate reference standard
- a concordance study (to show agreement with currently used tests)
- interventional studies
- prospective observational studies (including real-world evidence).

For DHTs that drive a diagnosis, test accuracy alone does not demonstrate clinical utility and may need to be linked to existing studies (including studies on other technologies) reporting the downstream clinical consequences of the diagnosis or test outcome.

Effectiveness of DHTs that treat a specific condition

One or more high-quality interventional studies (experimental or quasi-experimental design) to support the claimed benefits of the DHT, done in a setting relevant to the UK health and social care system and showing improvements in relevant outcomes, such as:

- clinically relevant outcomes

- patient-relevant outcomes.

The choice of study design should be appropriate for the intended purpose of the DHT. Randomised controlled trials would be preferrable where this study design is appropriate. High quality, comparative real-world study designs may also be acceptable.

The comparator should be a care option that reflects the current NHS care pathway, such as a commonly used active intervention.

User acceptability and engagement measures may also be useful.

Performance of DHTs that diagnose a specific condition

One or more high-quality studies done using the DHT, to support the claimed benefits of the test. This may include test accuracy studies, using an appropriate reference standard, or a concordance study to show agreement with current practice. Relevant outcomes may include:

- test accuracy
- time to diagnosis (if this is a claimed benefit of the test).

Test accuracy alone does not demonstrate clinical utility and may need to be linked to existing studies (including studies on other technologies) reporting the downstream clinical consequences of the diagnosis or test outcome.

Standard 15: show real-world evidence that the claimed benefits can be realised in practice

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 15

Evidence to show that the DHT has been successfully piloted in the UK health and social care system, showing that it is relevant to:

- current service provision in the UK (for tier A DHTs) or
- current best practice in the UK (for tier B and tier C DHTs).

This may include a statement from pilot site(s) to confirm that during testing, the DHT:

- was acceptable to users
- performed its intended purpose to the expected level
- successfully integrated into current service provision or current best practice
- caused no unintended negative impacts on service users or services
- showed improvements in outcomes (costs saved, efficiencies achieved, health and care improvements)
- was used in line with expectation (who, how, for how long).

For tier C DHTs intended to be used for critical conditions or situations, this real-world evidence can be used to reduce uncertainties in any interventional studies that have been done to meet standard 14.

For DHTs that are expected to have high costs or system impact (such as requiring significant service redesign), then higher levels of real-world evidence may help to reduce uncertainty. This could include larger-scale studies or longer-term outcomes.

For DHTs whose performance may be affected by local deployment factors (such as DHTs using artificial intelligence), this may include deploying the DHT to run offline or evaluating it 'in silent mode'.

Silent mode evaluations allow the DHT's performance on local data inputs to be observed (but not used in care decisions), before the DHT is integrated into clinical or care pathways. This can show whether the DHT's performance reaches the expected levels using input data generated in the local environment.

Standard 16: the company and evaluator should agree a plan for measuring usage and changes in the DHT's performance over time

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 16

The company and evaluator should agree a plan for ongoing data collection to report:

- ongoing usage of the DHT in the target population in line with the expected usage profile (to be agreed at commissioning)
- anonymised, aggregate data to show service user outcomes or any other outcomes collected by the DHT (where appropriate).

In addition, for DHTs whose performance is expected to change over time (such as DHTs that use artificial intelligence or machine-learning algorithms, or DHTs that are expected to be updated in subsequent versions), the company and evaluator should agree on post-deployment reporting of changes in performance. This may include:

- future plans for updating the DHT, including how regularly the algorithms are expected to retrain, re-version or change functionality
- the sources of retraining data, and how the quality of this data will be assessed
- processes in place for measuring performance over time, to detect any impacts of planned changes or environmental factors that may impact performance
- processes in place to detect decreasing performance in certain groups of people over time
- whether there is an independent overview process for reviewing changes in performance
- an agreement on how and when changes in performance should be reported and to whom (evaluators, patients, carers, health and care professionals).

If the intended purpose of the DHT changes, or if additional functions are added that change the intended purpose and ESF classification of the DHT, then a new evaluation should be done. For DHTs that are medical devices, changes to the intended purpose would require regulatory re-evaluation and may result in reclassification as a medical device, and additional evidence to support the change.

Delivering value

Standard 17: provide a budget impact analysis

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 17

Provide a budget impact analysis relevant to the setting the DHT is used in. This can be done using information about the value proposition given in response to standards 10 to 13, and the outcomes from studies shown in standard 14, or the real-world evidence in standard 15.

For tier B and C DHTs, the budget impact analysis should include:

- size of target population and uptake estimates
- all direct costs associated with the technology and implementing the technology, including cost of the technology (purchasing, updating, maintenance), costs of staffing and training, costs of supportive IT infrastructure needed to implement the technology
- all direct costs associated with the comparator
- relevant indirect costs associated with the technology and the comparator, reference test or current practice.

For tier A DHTs, a simpler analysis may be more appropriate. This would include a comparison of direct and indirect costs and resource impacts between the DHT and current practice.

Estimates of resource use should include:

- length of hospital or care home stay
- number of hospitalisations
- outpatient or primary care consultations
- changes in infrastructure, use and maintenance.

Show that the costs used are relevant to the UK health and care system and they should relate to NHS and personal social services resources. Suitable sources include:

- NHS reference costs
- NHS national tariff
- Patient level information and costing system (PLICS) data collections.

Show that the estimates for resource use are based on clinical practice, which can be based on data from:

- a clinical study
- real-world data including from pilot studies
- information obtained from relevant clinical or social care professionals
- other appropriate sources.

State the source of the data for the cost and resource estimates. State whether the estimates are recognised as accurate and comprehensive by a relevant health and social care professional. Include any expected variations for different groups of service users.

Explore the uncertainty of the estimate obtained from the budget impact analysis by varying the assumptions used (for example, using best- and worst-case values for target population size, resource use or outcomes from the performance studies in standard 13), to investigate how these variations impact the analysis.

Standard 18: for DHTs with higher financial risk, provide a cost-effectiveness analysis

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 18

We define a DHT with higher financial risk as: where the costs of commissioning, purchasing or implementing the DHT are deemed to be substantial within the context of the relevant budget and system priorities. This will vary between different commissioning organisations, and contributing factors may include:

- coverage of commissioning of the technology, for example for large-scale or national adoption of the DHT
- the extent of changes needed within an organisation to use the DHT; this could include changes to IT systems, staffing or care pathways
- the extent of implementation costs needed to use the DHT.

When needed, a cost-effectiveness analysis in the form of cost–utility or cost-consequences analysis should be done to inform the budget impact analysis in standard 17. A cost-effectiveness analysis can be done if a DHT:

- provides similar or greater benefits at higher cost
- provides marginally lower benefits for significantly lower costs.

Cost–utility analysis (described in section 4.2.14 of the NICE health technology evaluations manual) uses utility as a common outcome. It considers people's quality of life and the length of life they will gain as a result of an intervention or a programme. An appropriate standard measure should be used for utility data (such as EQ-5D).

If a cost–utility analysis is not possible (for example, when outcomes cannot be expressed using a utility measure such as the QALY), a cost–consequences analysis may be considered (see developing NICE guidelines: the manual). A cost-consequences analysis can consider all the relevant health and non-health effects of a DHT across different settings and reports them without aggregation. The UK Health Security agency has published advice on using cost–consequences analysis for DHTs. NICE uses cost-comparison analysis to develop guidance on DHTs that are likely to be cost saving. This is a similar approach to cost-consequences analyses.

The NICE health technology evaluations: the manual gives further guidance on how different health economic analyses can be done.

For all analyses, explore the uncertainty of the obtained estimate by using sensitivity and scenario analyses.

Deployment considerations

Standard 19: ensure transparency about requirements for

deployment

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 19

The company should provide clear descriptions of the data used in deployment. This should include:

- a full description of the input data for the DHT that includes a data dictionary
- quantifying the level of tolerance that the DHT has for incomplete data (such as inputs that are missing or of insufficient quality), and how outlier data is handled
- a data flow map for deployment of the DHT to allow efficient deployment
- data requirements for the DHT, such as specific data formats, data standardisation requirements (such as DICOM), completeness or quality
- the minimum infrastructure requirements for deploying the DHT.

Standard 20: describe strategies for communication, consent and training processes to allow the DHT to be understood

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 20

The company must ensure that appropriate communication strategies are in place for service users and health and care professionals, to describe the outputs, key features, benefits and limitations of the DHT. This may include providing a model card to allow people to understand when and whether to use the DHT in a person's care.

Within the communication and training, the company should describe the DHT's outputs, and how these outputs should be interpreted. For example, different DHTs could provide outputs that are:

- risk scores
- probabilities of different diagnoses

- recommendations for other tests.

The company should describe their planned approach for training end users of the DHT to allow the benefits of the DHT to be realised in practice.

If service user consent is needed, the company should describe this process.

Standard 21: ensure appropriate scalability

Applies to DHTs in tiers A, B and C.

Information that can be used to meet standard 21

The company should ensure that load testing has been done, to show that the DHT can perform to the scale needed (for example, having servers that can scale to manage the expected number of service users).

Describe the process for load testing and how this relates to the expected uptake for the DHT.

Section D: Early deployment standards for evidence-generation programmes

It can be challenging for companies whose digital health technologies (DHTs) are at an early development stage, to generate the evidence needed to meet the requirements of the evidence standards framework (ESF). To address this challenge, evidence-generation programmes exist to support companies to develop the evidence base for their DHT. These programmes support the piloting or early deployment of the technology to facilitate evidence generation to demonstrate its effectiveness, place in the care pathway and economic impact.

To be included in such evidence-generation programmes, it is assumed that the DHT is a commercially viable product that has been through its design, development and validation phases, and has obtained the necessary regulatory approval (where needed) or appropriate technical standards to ensure its safety and reliability.

To create the early deployment (ED) subset of standards, we have removed standards that are likely to only be met by DHTs at a later point in their evidence-generation plan. Evidence-generation programmes are run by different organisations across the NHS and so are likely to have individual requirements, which may include, for example, some relevant clinical data from feasibility studies.

The ED subset of the ESF standards could be used to evaluate the suitability of DHTs for inclusion in evidence-generation programmes. The ED subset includes 16 standards:

- **Design factors:** The 9 standards identify key aspects of the design process that impact the DHT's value to the health and care system, including ensuring the technology has the appropriate technical standards for safety and reliability. Standards 7 to 9 do not apply to tier A DHTs.
- **Describing value:** The 4 standards apply across all DHTs and present the value proposition of the technology.
- **Demonstrating performance:** 1 standard that shows the company and the evaluator should reach an agreement for ongoing data collection.
- **Deployment considerations:** 2 standards that describe the deployment considerations

and the communication strategies that are in place for service users and health and care professionals.

Summary of early deployment standards

Tables 8 to 11 summarise the 16 ED standards that are suggested for early deployment technologies being considered for an evidence-generation programme.

Table 8 Design factors standards included in ED standards

Standard	Tiers to which the evidence standard applies
1: the DHT should comply with relevant safety and quality standards	A, B and C
2: incorporate intended user group acceptability in the design of the DHT	A, B and C
3: consider environmental sustainability	A, B and C
4: consider health and care inequalities and bias mitigation	A, B and C
5: embed good data practices in the design of the DHT	A, B and C
6: define the level of professional oversight	A, B and C
7: show processes for creating reliable health information	B and C
8: show that the DHT is credible with UK professionals	B and C
9: provide safeguarding assurances for DHTs where service users are considered to be in vulnerable groups, or where peer-peer interaction is enabled	B and C

Table abbreviations: DHT, digital health technology; ED, early deployment.

Table 9 Describing value standards included in ED standards

Standard	DHTs it applies in
10: describe the intended purpose and target population	A, B and C
11: describe the current pathway or system process	A, B and C

Standard	DHTs it applies in
12: describe the proposed pathway or system process using the DHT	A, B and C
13: describe the expected health, cost and resource impacts compared with standard or current care or system processes	A, B and C

Table abbreviations: DHT, digital health technology; ED, early deployment.

Table 10 Demonstrating performance standard included in ED standards

Standard	DHTs it applies in
16: the company and evaluator should agree a plan for measuring usage and changes in the DHT's performance over time	A, B and C

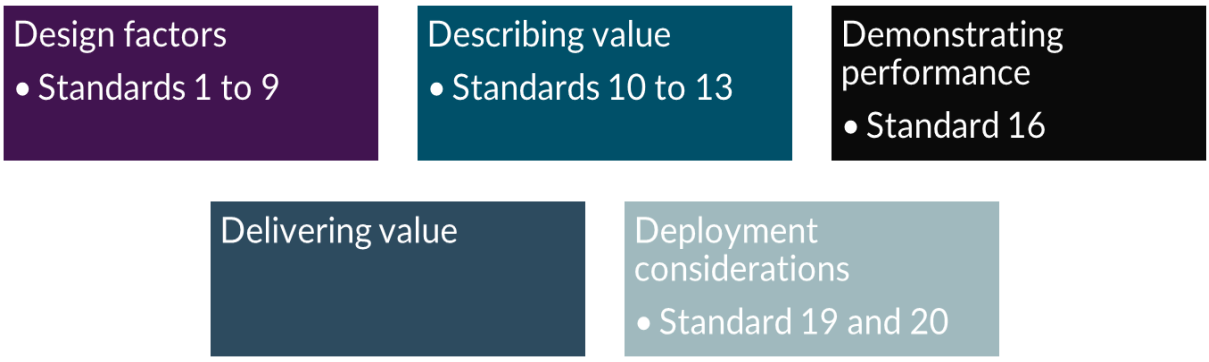
Table abbreviations: DHT, digital health technology; ED, early deployment.

Table 11 Deployment considerations standard included in ED standards

Standard	DHTs it applies in
19: ensure transparency about requirements for deployment	A, B and C
20: describe strategies for communication, consent and training processes to allow the DHT to be understood by end users	A, B and C

Table abbreviations: DHT, digital health technology; ED, early deployment.

Figure 3 The standard subset for ED



Update information

August 2022: We updated the framework to:

- include evidence requirements for artificial intelligence (AI) and data-driven technologies with adaptive algorithms
- align digital health technology classifications with regulatory requirements
- make the framework easier to use
- outline a subset of early deployment standards that can be used within evidence generation programmes.

April 2021: We updated the framework document with changes in response to an ESF user survey, which ran from October to December 2019. The following changes have been made:

- The names of the evidence tiers have been changed to avoid any confusion with CE marking categories:
  - Tier 1 is now Tier A: system impact
  - Tier 2 is now Tier B: understanding and communicating
  - Tier 3a and 3b have been combined and are now Tier C: interventions
- The evidence requirements for each evidence tier remain the same but we have changed how they are presented. Instead of having to combine up to 3 tables of evidence, we've put all evidence requirements into a single table for each tier.
- We have improved table 1 Table 1 ESF evidence tiers and classification groups to make it easier to understand which DHTs fit into each functional classification.

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