NICE National Institute for Health and Care Excellence

Evidence standards framework for digital health technologies: user guide

Implementation support

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In this guide

The user guide contains information on:

- the purpose of NICE's ESF
- who should use the ESF and how
- how the ESF fits into the wider digital health technology (DHT) assessment ecosystem
- an introduction to using the ESF
- how to classify a DHT using the ESF
- how to identify the standards relevant to a DHT using the ESF.

The guide also contains some frequently asked questions relating to the ESF and introduces the reader to terms commonly used in the ESF and the user guide.

The ESF and who it is for

The ESF has been produced to promote more consistency in the evaluation of digital health technologies (DHTs) across the NHS.

The intended users are:

- commissioners and evaluators in the health and care system making purchasing decisions; they can use the ESF to help them to decide whether to commission a DHT in their organisation
- companies developing DHTs for use in the health and care system.

The ESF should help evaluators, decision makers and purchasers to make more informed and consistent decisions when commissioning or buying DHTs. If the ESF is widely adopted by evaluators, it should help ease the burden on companies because they can present the same information for different evaluators and commissioning decisions.

The ESF will help companies to understand what information is needed about the DHT and what evidence should be created throughout the life cycle of the DHT to support uptake in the health and care system.

How the ESF fits in the DHT assessment ecosystem

Regulation and technical standards

The NICE ESF is designed to stand alongside other standards, regulation and guidance from national bodies about using digital health technologies (DHTs), including data-driven technologies in the UK health and care system.

The regulatory landscape for digital healthcare and artificial intelligence (AI) are still at a formative stage. Regulation and best practice guidance are likely to change significantly over the coming years as we learn how best to manage the risks and benefits of digital and AI healthcare.

In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for the regulation of safety, quality and efficacy of medical devices including software as a medical device. The MHRA has announced the Software and AI as a Medical Device Change Programme, which aims to ensure that medical device regulation is fit for purpose for software, including AI.

The Care Quality Commission (CQC) regulates and inspects health and social care services in England. CQC does not provide detailed guidance on the adoption of technologies but some technologies that are used in the delivery of care may be within the remit of CQC inspections.

We will continue to review and update the NICE ESF to ensure that it is up to date with the regulatory landscape in the NHS.

The exact regulatory requirements applicable to each DHT will depend on its intended purpose and where in the health and care system it is intended to be used. Many of the DHTs covered by the ESF are not within the remit of regulation by the MHRA or the CQC. However, there are technical standards and guidance that are relevant to these DHTs. For example, a DHT designed to improve efficiency should meet the requirements of ISO 82304-1 for healthcare software.

Standards in the health and care system

The NHS has also developed some standards to help ensure DHTs used within the health and care system meet the expected technical standards. The Digital Technology Assessment Criteria (DTAC) is designed to give staff, patients and citizens reassurance that all DHTs used in the NHS meet national standards. These criteria are based on legalisation and best practice across 5 categories. DHTs can pass or fail in 4 categories: clinical safety, data protection, technical security and interoperability, and obtain a score in the 5th: usability and accessibility.

Health technology evaluation and NICE

NICE has produced the ESF to help evaluators in the health and care system to assess DHTs. NICE also develops guidance on DHTs, does its own evaluations of DHTs that are regulated as medical devices or in vitro diagnostics, and publishes guidance or advice as a result of these evaluations.

NICE guidance includes an in-depth evaluation of the clinical and cost effectiveness of a DHT that is considered for use in the NHS across England. The evaluation is usually done within the NICE medical technologies evaluation programme (MTEP) or diagnostics assessment programme (DAP), depending on the intended purpose of the DHT. The evaluation process takes around 1 year and includes the appraisal of the evidence by an independent committee supported by professional and patient experts. It results in a recommendation about whether the DHT should be used by the NHS or not. More information about the development of NICE guidance for DHTs is in the section on MTEP in NICE health technology evaluations: the manual.

NICE advice is produced by a faster process that does not include a recommendation on NHS use. Instead, NICE advice (such as medtech innovation briefings; MIBs) includes a description of a regulated medical device or in vitro diagnostics, and its place in the care pathway, a critical appraisal of the available evidence and some expert opinion. More information is on NICE's webpage on medtech innovation briefings.

Meeting the evidence standards in the ESF does not constitute a NICE evaluation, NICE recommendation or endorsement, nor NICE guidance. The ESF is not an entry point to these programmes.

The ESF has been designed to include some areas that are common to NICE evaluation

programmes. These include demonstrating effectiveness and showing a value proposition. An assessment of health inequalities would also be included in a NICE evaluation. The deployment considerations included in the ESF would be considered to be outside of scope for NICE guidance or advice.

How to use the framework

Deciding whether the technology is within the scope of the framework

We developed the ESF for a broad spectrum of digital health technologies (DHTs) that are of interest to the health and social care system.

If you can answer all the following 4 questions with 'Yes', then it is **likely** that the technology is covered by the ESF:

1. Is the technology an app, software or online platform that is intended to benefit people's health or care or the wider health and social care system?
2. Does the technology have a medical, health or wellness, or system efficiency purpose?
3. Does the technology offer value to the health and social care system?
4. Is the technology available and likely to be commissioned in the UK health and social care system?

If you answer 'Yes' to any of the following questions, then it is **unlikely** that the technology is covered by the ESF:

1. Is the technology designed for training health or care professionals or facilitating data collection in research studies?
2. Is the technology and software integral to or embedded in a medical device? Embedded software is likely to be regulated as software in a medical device (SiMD) rather than software as a medical device (SaMD).
3. Is the technology a surgical robot?

Deciding what category the technology falls in

To decide what category the DHT falls in, we have used a tiered approach (consisting of

3 tiers) based on the potential risk to the person whose health or wellbeing is affected by the DHT, and to the system:

- Tier A: the technology is intended to release costs or staff time or to improve efficiency.
- Tier B: the technology is intended to help patients and citizens to manage their own health and wellness.
- Tier C:
  - the technology is intended to treat or diagnose a specific condition or guide treatment, diagnosis and care choices
  - the technology is intended to have direct health outcomes
  - the technology is a medical device or an in vitro diagnostic or a screening tool.

Tier A has the lowest associated risk and tier C has the highest associated risk. Tier A includes only 1 category, whereas tier B includes 3 categories and tier C includes 4 categories.

The categories are defined by the intended purpose of the DHT. Tables 1 to 3 describe examples of technologies in the different tiers. Further examples can be found in the ESF classification examples spreadsheet.

To identify the category for a technology, consider the tier and category descriptions in the following 3 tables indicating the intended purpose of technologies within that group. The examples shown and those included in the ESF classification examples spreadsheet are designed to help users understand how the classification works in practice. These examples have been classified based on their publicly available descriptions.

Table 1 Examples of tier A technologies

Category within tier	Example technologies
System service There are no direct patient, health or care outcomes from this technology.	• An app intended for documenting patient encounters via a mobile or desktop. • An app intended to work as a wireless microphone, optimised for use with specific software.

Table 2 Examples of tier B technologies

Category within tier	Example technologies
Communicating about health and care Communicating with health professionals or others, to help service users to manage their health and care.	• A messaging service intended for within-team and practitioner-to-patient messaging.
Health and care diaries Health and care diaries to help service users to manage their own health and wellness.	• An app intended for tracking vital health and lifestyle metrics using automatically captured data, as well as data manually entered by the user • An app intended for patients to track treatment and record fatigue, appetite and pain in order to help spot trends and improve care during breast cancer treatment

Category within tier	Example technologies
Promoting good health Population-level information to help people and service users to maintain healthy lifestyles and manage conditions.	• An app intended to support mental health by providing courses on mindfulness and meditation, and sleep-specific solutions such as relaxing sleep music and sleepcasts. • An app intended to provide information and self-care advice to help manage the symptoms of lymphoedema.

Table 3 Examples of tier C technologies

Category within tier	Example technologies
Inform clinical management Digital health technologies (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. Information provided by the DHT will not trigger an immediate or near-term action.	• An app intended for heart health monitoring that reports the results of heart rates measured by a smartphone's camera. • An app intended for diabetes management including tracking and diary keeping options.
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, or to guide next diagnostics or next treatment interventions.	• Software intended to analyse data and estimate fractional flow reserve from coronary CT angiography. • A portable electrocardiogram recorder for detecting atrial fibrillation, compatible with an app intended to record and share the results with a healthcare professional.

Category within tier	Example technologies
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.	• An artificial intelligence (AI) algorithm intended to fast-track the diagnosis of suspected lung cancer and reduce the radiology department's workload • An implantable cardiac monitor that can monitor heart rhythms for several years; algorithms on the device intended to detect potential atrial fibrillation and send the data for clinician review
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.	• An app intended to facilitate self-management for chronic obstructive pulmonary disease, which includes pulmonary rehabilitation. • A web-based programme intended for self-help sleep improvement based on cognitive behavioural therapy for insomnia.

Some DHTs might have intended purposes that fall into more than 1 tier, in which case, the highest tier should be used to define its tier. For example, a DHT might provide both a health diary and treatment for a condition. Of these 2 intended purposes, providing treatment is the higher risk. So, this technology would be classed as a tier C technology.

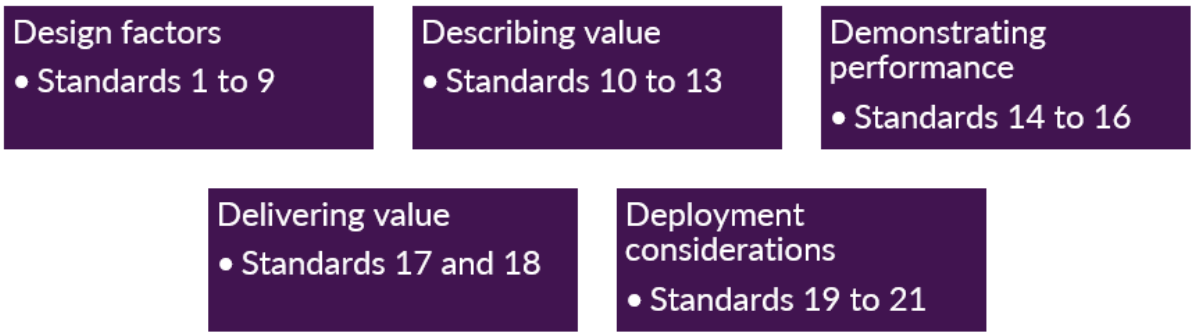
Some DHTs have various levels of intended purpose within the same tier depending on the level of service that is commissioned. For these technologies, the highest category that is being considered for commissioning should be used to define its classification. This is particularly relevant for tier C technologies for which evidence requirements differ between the 4 categories. For example, a DHT that enables data sharing for a specific

condition with a healthcare professional for later review and that also provides treatment could be classed as tier C: inform clinical management or treat a condition, depending on what level of service is being commissioned.

Deciding which evidence standards are relevant

The ESF includes 21 standards that are arranged across 5 areas of a DHT's life cycle: design factors, describing value, demonstrating performance, delivering value and deployment considerations (for more detail, see the section on how the framework was developed).

Figure 1 The 5 groups of evidence standards relating to different aspects of the product life cycle



Most standards (17 out of 21) are tier agnostic, meaning that they are relevant to technologies in tiers A, B and C.

- **Design factors:** The 9 standards cover general aspects of good design principles and identify key aspects of the design process that impact the DHT's value to the health and care system. Most of these areas are also in the remit of published technical standards, as referred to in the ESF standard 1, and might be within the remit of regulation of medical devices or in vitro diagnostics. The extent to which the 9 areas are covered in the different applications might vary. Of the 9 standards:
  - Standards 1 to 6 apply to all tiers.
  - Standards 7 to 9 apply to tiers B and C (these standards are less relevant to technologies in tier A). Standard 7 addresses items such as reliable health information, standard 8 addresses credibility with UK professionals, and standard 9 addresses safeguarding assurance.

- **Describing value:** The 4 standards describe the system service, wellness, care or health problem to be addressed by the DHT. They provide key information about the target population and positioning of the technology in the health and care system. They also identify, value and qualitatively compare the costs and outcomes of the DHT to inform the value proposition of the DHT. For DHTs that are early in their life cycle, we acknowledge that numerical estimates for costs and outcomes or benefits might not be available, and so a qualitative description might be sufficient. The 4 standards provide important background information that clearly specifies the problem the DHTs are addressing and helps to inform the assessment of the evidence described in the demonstrating performance and delivering value standards. Companies might work with evaluators to refine the value proposition of the DHT. The 4 standards apply to all tiers.

- **Demonstrating performance:** The 3 standards describe the evidence to establish the level of the DHT's performance. Proven clinical effectiveness is important for considering the potential patient and health benefits of DHTs that treat and diagnose or guide clinical care choices. Standard 14 is specific to tier C technologies to demonstrate clinical effectiveness. Likewise, proven real-world performance is important for considering the potential use of the DHTs in clinical practice. Monitoring performance ensures that the DHT continues to deliver its anticipated value after deployment and implementation. This is particularly important for data-driven technologies that may update frequently. Standards 15 and 16 are relevant to all technologies. Monitoring after deployment is likely to also be in the remit of the Medicines and Healthcare products Regulatory Agency (MHRA) regulations. The type of evidence presented to the different authorities might vary depending on the remit and process of the specific evaluation.

- **Delivering value:** The 2 standards help to understand the affordability and value for money of the DHT. They measure and quantitively compare the costs and outcomes identified in the describe value standards (standards 10 to 13). All DHTs should present a budget impact analysis (BIA) so the evaluator can understand the potential impact of the DHT on their budget when adopting the DHT. A BIA only considers costs and benefits that are monetised; these costs and benefits can relate to cash (for example, consumables) or capacity (for example, hospital admissions). For DHTs with higher financial risk (that is, when the costs of commissioning, purchasing or implementing the DHT are deemed to be substantial within the context of relevant budget), a cost–utility analysis or cost–consequences analysis might be needed to understand the value for money of the DHT.

- **Deployment considerations:** We acknowledge that deployment of DHTs might be more complex than deployment of pharmaceuticals and we identified 3 key deployment considerations. These considerations are important for successful deployment and implementation of a DHT but do not directly contribute to the value of a technology. The 3 standards apply across all tiers.

ESF standards that are especially relevant for data-driven DHTs

The ESF is also relevant for data-driven DHTs that have fixed or adaptive machine learning algorithms. These technologies might have increased risks not seen for other technologies; therefore, we developed some standards with this in mind. These standards are not exclusively for data-driven DHTs but include aspects that are more relevant to these technologies. These standards are:

- **Design factors, standards 4, 5 and 6:**
  - Consider health and care inequalities and bias mitigation.
  - Embed good data practices in the design of the DHT.
  - Define the level of professional oversight.
- **Demonstrating performance, standards 15 and 16:**
  - Show real-world evidence that the claimed benefits can be realised in practice.
  - The company and evaluator should agree a plan for measuring changes in the DHT's performance over time.
- **Deployment consideration, standards 20 and 21:**
  - Ensure transparency about requirements for deployment.
  - Describe strategies for communication, consent and training processes to allow the DHT to be understood by end users.

ESF standards for early deployment DHTs

We acknowledge that some promising DHTs may not have all the evidence to support their value-for-money claim and that such evidence might best be generated in a real-world setting through an evidence-generation programme. The company and evaluator, in this

case the potential early adopter, should assess the feasibility of the evidence generation within the timelines of the evidence-generation programme. The evidence-generation plan should be designed so that the generated evidence should support full deployment of the DHT following the evidence-generation programme. This means that DHTs entering the programme should have a certain maturity so that the evidence-generation plan can address gaps in the evidence and increase the likelihood of a successful completion of the evidence-generation programme. We have developed an early deployment subset of 16 standards which might help identify DHTs that can be considered for such programmes. Evidence-generation programmes might be initiated by different authorities and therefore might differ in their requirements and length of programme. The early deployment subset contains:

- **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 tiers 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.

Figure 2 The subset of standards relevant to digital health technologies (DHTs) that can be considered in an evidence-generation programme during early deployment

Example use cases

Evaluators who want to purchase or commission DHTs

Evaluators who are assessing DHTs to inform a purchasing or commissioning decision can use the NICE ESF as a standardised way of assessing the potential value of a DHT. This could provide a way for evaluations to be done consistently between DHTs and provide a structured format for information relevant to the evaluation.

The evaluator would work with the company to identify the intended purpose of the DHT and its appropriate evidence tier. The evaluator can then ask the company to provide any evidence needed to meet the relevant evidence standards.

For the standards involving ongoing evidence-generation plans, the company and evaluator would work together to agree what performance and usage data would be collected, and how and when this would be reported to the evaluator.

Evaluators in the health and care system who are appraising the value of a DHT

Evaluators may use the ESF to assess the suitability of a DHT for inclusion in innovation programmes, or to compare DHTs within the same clinical area.

The evaluator would identify the intended purpose of the DHT and its appropriate evidence tier, and would assess the breadth and relevance of the available evidence.

Companies who want to sell a DHT to the health or care system

Companies who have a DHT that they believe is ready for adoption in the health and care system at a local, regional or national level can use the ESF to show that they meet the evidence standards relevant to their DHT.

The company would work with the evaluator to identify the intended purpose of the DHT and its appropriate evidence tier. The company would provide any evidence needed to meet the relevant evidence standards. The NICE ESF describes the evidence that is likely to be needed to present to an evaluator for assessment.

Companies who want to generate evidence for their DHT within a health or care setting

Companies who have developed a DHT that is a prototype at planned operational level and is ready for demonstration in the health and care system, can use the ESF to understand the level of evidence they need to produce to aid commissioning at a later stage.

The company would work with the evaluator to identify the intended purpose of the DHT and its appropriate evidence tier. The company and evaluator would work together to agree what performance and usage data would be collected, and how and when this would be reported to the evaluator.

Companies who are at early stages of product development

Companies who are at the early stages of product development can use the NICE ESF as guidance to understand the level of evidence needed to be considered for an evidence-generation plan.

Examples of ESF use cases can be found here.

Why the framework was developed

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

DHTs are rapidly developed and updated, with new versions being regularly released. There is generally less or lower quality evidence for DHTs 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 DHTs around data security, privacy and confidentiality, which are difficult to assess by non-specialists. More and more DHTs also incorporate machine learning (a form of artificial intelligence [AI]), which poses additional challenges such as model adaptiveness, device autonomy, limited output explainability and the consequences of human–technology interaction in clinical settings.

These challenges have created barriers to DHTs 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 DHTs in the UK health and social care system.

The evidence standard supports principle 11 of the Department of Health and Social Care's guide to good practice for digital and data-driven health technologies, which states that the companies should generate evidence that the product achieves clinical, social economic or behavioural benefits, and may also be relevant for other principles.

How the framework was developed

NICE developed the first version of the ESF in 2018 and has published details separately on how the evidence standards were developed (Unsworth et al. 2021). 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 June 2021, NICE started a wider update of the ESF, which included:

- alignment with regulatory frameworks in development
- addressing stakeholder feedback obtained via a survey in October 2019
- inclusion of digital health technologies (DHTs) that use adaptive algorithms (that is, algorithms that continually change).

Experts in artificial intelligence (AI) in healthcare at Birmingham University, Imperial College London and the Turing Institute did research and advised NICE around the challenges of DHTs with adaptive algorithms and how these can be addressed by appropriate evidence standards in the framework. Between October 2021 and March 2022, the following stakeholders provided comments and feedback:

- industry representatives, developers and companies
- healthcare evaluators
- regulators
- academic experts in health technology assessment, DHTs and AI
- clinical experts with special interests in DHTs and AI
- national and international health technology assessment organisations
- organisations responsible for promoting innovations such as Academic Health Science Networks (AHSNs), Digital Accelerators and the NHS AI Lab.

The work carried out by the academic consortium is described in the accompanying report by the academic consortium led by Imperial college and in the report by Unsworth et al.

(2022).

During this update of the ESF, the NICE team also worked closely with other national bodies interested in the evaluation of DHTs such as Medicines and Healthcare products Regulatory Agency (MHRA), Health Technology Wales and the Scottish Health Technology Group. There was also significant interest from overseas including health technology assessment (HTA) organisations who are also exploring how these types of technologies should be evaluated. During the revision of the ESF we had discussions with groups working in France, Australia, Italy and Latin America.

We updated the classification system based on stakeholder feedback and to align with medical device regulatory frameworks in development. For tier C, we aligned the classification groups to the software as a medical device (SaMD) classification framework proposed by the International Medical Device Regulators Forum (IMDRF), of which the MHRA is a member. For tier B, we simplified the classification groups so that most tier B technologies can be covered by 1 of the 3 groups. There are no changes to tier A.

We updated the evidence standards based on stakeholder feedback, and research and input from our academic partners. These changes include:

- updating and amending existing standards
- expanding standards so they are also relevant to DHTs with adaptive algorithms
- adding new standards such as standards for environmental sustainability and good data practice
- restructuring the standards to reflect a DHT's life cycle.

The updated ESF covers 5 broad areas: design factors, describing value, demonstrating performance, delivering value and deployment considerations (see the section on deciding which evidence standards are relevant).

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

Frequently asked questions

The ESF and its relation to other evaluations in the health and care system

What is the difference between the ESF and medical device regulation by the Medicines and Healthcare products Regulatory Agency?

Medical devices and in vitro diagnostics regulation, which is under Medicines and Healthcare products Regulatory Agency's (MHRAs) remit in the UK, is a legally mandated requirement for any digital health technology (DHT) within remit for regulation. The aim of regulation is to ensure that only safe and effective medical devices can be placed on the market. MHRA has provided guidance on medical device stand-alone software including apps to help companies to understand whether their DHT is within remit for regulation as a medical device or in vitro diagnostics.

The ESF is a set of non-mandated standards designed by NICE. The ESF describes the types and levels of evidence that different types of DHT should be able to demonstrate in order to be commissioned in the UK health and care system. The ESF standards include good design practices, describing and evidencing a value proposition, demonstrating clinical effectiveness and some issues relating to effective deployment of DHTs.

The ESF can be used to evaluate any DHT that is commissioned in the UK health and care system, regardless of whether it is regulated as a medical device or in vitro diagnostics, or not.

My DHT is a medical device and is UK Conformity Assessed marked, do I have to duplicate evidence presented to the UK-approved bodies in the ESF?

Within the ESF, there are some topics, such as user acceptability and demonstrating effectiveness, that might also be within the scope of regulations by MHRA for UK Conformity Assessed (UKCA) marking. It should not be assumed that these standards are

met based on UKCA marking alone, and relevant details should be provided for the evaluator to understand the available evidence.

What is the difference between the ESF and the Digital Technology Assessment Criteria?

Both the Digital Technology Assessment Criteria (DTAC) and the NICE ESF help assess DHTs that enter the health and care system in the UK. They also help companies to understand what is needed when entering the health and care system. The DTAC covers clinical safety, data protection, technical security, interoperability and usability and accessibility standards. The ESF covers standards on design factors, describing value, demonstrating performance, delivering value and deployment considerations, so that companies can demonstrate and evaluators can evaluate the effectiveness and value for DHTs. Most standards covered in the ESF are not within the scope of DTAC. There might be topic overlap with a few standards such as ESF standard 1 and D1 in the DTAC around user acceptability.

My DHT passed the DTAC, do I have to duplicate evidence presented during the DTAC assessment in the ESF?

The DTAC covers clinical safety, data protection, technical security, interoperability and usability and accessibility standards. The ESF covers standards on design factors, describing value, demonstrating performance, delivering value and deployment considerations, so that companies can demonstrate and evaluators can evaluate the effectiveness and value of DHTs. Most standards covered in the ESF are not within the scope of DTAC. There might be topic overlap with a few standards such as ESF standard 1 and DTAC D1 around user acceptability. In such cases, the same evidence could be presented and the company might refer to the DTAC assessment.

What is the difference between NICE guidance and the ESF?

The ESF is a non-mandated tool that is designed to be used by evaluators in the health and care system to help them to decide whether to commission a DHT within their organisation. NICE guidance is produced by NICE teams, according to published methods. NICE guidance involves a more in-depth evaluation of the clinical and economic evidence for a DHT and results in a national-level recommendation on whether the technology should be used.

NICE's Centre for Health Technology Evaluation (CHTE) produces guidance across a range of health technologies, including DHTs. The health technology evaluation methods and processes used are described in NICE health technology evaluations: the manual. This manual describes the evidence considered in the evaluations to demonstrate the effectiveness of the technology and its economic value. Only DHTs that are UKCA or CE marked (under the transition agreement) are considered for NICE guidance development. The identification and selection for technologies including DHTs for guidance development are described in NICE health technology evaluation topic selection: the manual.

The ESF has been designed to apply to a broader range of DHTs, including tier A and tier B DHTs that are unlikely to be regulated as medical devices. The intended users of the ESF are commissioners and evaluators in the health and care system making purchasing decisions, and companies developing DHTs for use in the health and care system. The ESF is a tool to guide local evaluations, not a NICE evaluation process, and NICE does not use the ESF to produce NICE guidance. The ESF is a framework that has been produced to promote more consistency in the evaluation of DHTs across the NHS.

There is a common approach between the methods used for NICE guidance development and the standards described in the ESF. Both use an evidence-based approach to ensure clinical effectiveness and value for money of the technologies used in the health and care system. NICE guidance identifies technologies for national adoption and so requires a detailed systematic review of the evidence, and its recommendations are based on independent committee decisions. The ESF is designed for local or regional evaluations of any DHT and so involves a simpler evaluation process and usually requires lower levels of evidence, for example, system service DHTs do not need clinical studies.

What is the difference between NICE medtech innovation briefings and the ESF?

NICE also produces medtech innovation briefings (MIBs). These summarise available information on a technology including the description of the technology, its use, a review of the relevant published evidence and the likely costs of the DHT. A MIB is NICE advice about a medical device or diagnostic and does not include recommendations about the use of the technology.

The ESF has been designed to apply to a broader range of DHTs, including tier A and tier B DHTs that are unlikely to be regulated as medical devices. The intended users of the ESF are commissioners and evaluators in the health and care system making purchasing

decisions, and companies developing DHTs for use in the health and care system. The ESF is a tool to guide local evaluations, not a NICE evaluation process, and NICE does not use the ESF to produce MIBs. The ESF is a framework that has been produced to promote more consistency in the evaluation of DHTs across the NHS.

If my DHT passes the ESF, does this mean it is approved by NICE?

Meeting the ESF standards does not mean that a DHT is approved by NICE, and does not mean that the DHT has NICE guidance. The ESF is intended to be a tool to help inform local evaluations of a DHT.

Does meeting the ESF standards equate to an NHS Approval for use?

No, meeting the ESF is not an approval for use within the NHS. For the innovator it means you have an appropriate level of evidence for the type of technology, and so that's a good start. However, the quality of the evidence will need to be assessed by local evaluators (clinicians and commissioners in the NHS) and decisions made locally about approving your technology for use. If an innovator is successful in these steps then it would be legitimate to say: Our technology has been assessed by [Evaluator] against the NICE ESF and has been approved for use in [Region/Locality] for the [intended purpose].

My DHT has a positive ORCHA review, what does this mean to evaluators?

ORCHA (Organisation for the Review of Health and Care Apps) adapted an earlier version of the ESF in its evaluation process. The updated ESF has a different remit to an ORCHA evaluation. Although evaluators in the health and care system might be guided by an ORCHA evaluation outcome, they might ask for additional evidence as outlined in the ESF.

ESF and reimbursement

Does meeting the ESF standards link to a reimbursement process?

The ESF does not link to any local or national reimbursement schemes. There is currently

no centralised reimbursement for DHTs in the UK.

How can I access help to develop evidence to support the claimed benefits of my DHT?

Here are some organisations that can support companies to develop their evidence-generation plans:

- The Academic Health Sciences Network (AHSN) is a network of 15 regional organisations that can help assess the commercial viability and economic potential, and support innovators to quantify and gather evidence of the impact, that the innovation could have on the health and care system.
- NICE Scientific Advice is a paid-for service that can help companies to develop high-quality evidence-generation plans.
- NICE Office for Market Access is a paid-for service that helps to speed up market access in the UK.

Funding opportunities exist from organisations including:

- National Institute for Health and Care Research (NIHR)
- Small Business Research Initiative (SBRI) Healthcare
- Innovate UK.

Supporting development of health economic evidence

What is a budget impact analysis? Which costs should be included?

The NICE ESF requires companies to provide a budget impact analysis (BIA) to inform the economic assessment of a DHT. The aim of a BIA is to give an estimate of the impact of the DHT on the decision-maker's budgets, usually over the next 5 years.

The key elements of a BIA include:

- estimating the size of the eligible population
- describing the current care pathway and the proposed care pathway using the DHT
- estimating the changes in resource use for the proposed care pathway, and what the difference in costs will be
- sensitivity analyses to investigate any uncertainties in the costs and assumptions used for the BIA.

For each cost or benefit item included in the BIA, the number of resources required or saved, and their unit costs should be reported. The totals for all cost items and monetary benefits should be provided. For these totals, a breakdown should be given, to show whether these costs and benefits relate to cash costs or savings (such as money spent on consumables) or capacity costs or savings (such as reducing hospital admissions) together with the incremental cost or saving.

Key points to note include:

- a BIA only considers costs and benefits which are monetised; these can relate to cash or capacity costs and benefits
- a BIA includes any VAT payable
- no discounting is used for the costs and benefits in future years
- the perspective is usually that of the budget holder or commissioner
- total costs and benefits are reported, rather than a cost per patient or per user.

Where can I find information to support the development of a BIA?

NICE provides a budget impact template alongside the ESF. This provides an initial guide for the development of a BIA. Because each DHT is unique, the information contained in the BIA and how the BIA is populated will depend on the DHT. The budget impact template includes a worksheet that provides links to useful cost and data sources. The template also links to examples of BIAs for technologies that have received positive NICE guidance. Other useful resources to learn more about BIA include

- ISPOR (International Society for Pharmacoeconomics and Outcomes Research) has developed principles of good practice for BIA, which is relevant to pharmaceuticals as well as DHTs.
- The UK Health Security Agency has also developed guidance on BIA for digital health technologies.

Where can I find information to support the development of a cost–utility analysis?

Section 4.2.14 of NICE health technology evaluations: the manual describes the cost–utility approach in more detail. The principles are relevant to pharmacological technologies and DHTs.

Where can I find information to support the development of a cost–consequence analysis?

Section 7 of the Developing NICE guidelines: the manual describes the cost–consequence approach in more detail. The UK Health Security Agency published some guidance on how to use a cost–consequence analysis to evaluate a DHT.

The remit of the ESF

Do DHTs that are already commissioned in the health and care system need to be evaluated using the ESF now?

The ESF has been designed to help inform a commissioning decision. DHTs that have already been commissioned could be evaluated using the ESF at their next recommissioning decision point.

Is the perspective in the ESF broader than a health technology assessment remit?

The revised ESF is based on standards presented in 5 groups: design factors, describing value, demonstrating performance, delivering value and deployment considerations.

The 4 describing value standards include information about the intended purpose of the technology, the target population and their current pathway of care, the proposed pathway with the DHT and the expected benefits associated with its use. This information is typically used to define the decision problem of a health technology assessment (HTA) process.

The HTA process usually focuses on evaluating the clinical effectiveness and value for money of a technology. These aspects are covered in the demonstrating performance and delivering value parts of the ESF.

The design factors standards include domains which may be assessed as part of the regulatory process but not all DHTs in the ESF will be medical devices and need regulation. Some of these standards, such as credibility with UK professionals and considerations of health and care inequalities, are important components of HTA.

The deployment considerations are a new area for the ESF, but these are essential for commissioners of data-driven DHTs. Feedback during the development of the standards highlighted the importance of understanding that many DHTs need significant recalibration when being implemented at a new site. For example, a DHT that is analysing imaging input data may produce slightly different results from different imaging hardware (even different models of the same machine). To help with this, standard 19 requests information about the requirements for implementing and embedding the new data-driven DHT. Similarly, we know that human factors play an important role in the successful implementation of these technologies. The effectiveness of data-driven DHTs depends on the effectiveness of the human team, not just on the AI algorithms. Staff need to understand and trust the new systems, and central to that will be communications and meeting training needs. This is covered in standard 20.

How should digital platforms be evaluated using the ESF?

A digital platform is defined as a digital tool, such as a website, that allows users access to several separate digital solutions (programmes or modules). This could be a single website that allows access to separate DHTs, such as different treatment modules or programmes for different mental health conditions.

The ESF is intended to be used to evaluate each digital solution or module within a platform independently. This is because each of these modules may be used by different patients or end users, and the health outcomes that can be used to measure their

effectiveness are different. This means that it is more appropriate to evaluate these separately.

Will the ESF be updated over time?

We have designed the ESF to reflect current best practice in the evaluation of DHTs, including AI technologies. We expect that best practice will change further over the coming years and we will continue to review and update the ESF as needed. We anticipate that the first review of the ESF will be in 2023, after MHRA publishes updated regulations for medical devices.

Terms used in the ESF

This section defines terms that have been used in a particular way for the ESF and the user guide.

Artificial intelligence

Artificial intelligence (AI) covers a range of computational methods for performing tasks that would ordinarily need human-level intelligence.

In healthcare, AI can be used to analyse large amounts of data to find patterns that are linked to an outcome, such as analysing data from MRI scans to find patterns that are linked to the presence of a tumour. AI can also be used to extract value from text information, such as patient notes, to identify patterns associated with health outcomes like risk of disease progression. Similarly, it can be used to analyse data on healthcare service use, to help to understand how to most efficiently deploy healthcare staff.

The precise definition and scope of the term 'AI' can vary between different contexts, and the level to which different digital health technologies (DHTs) use or rely on AI can vary greatly. In light of the variation in the way that the term 'AI' is used in healthcare, the NICE ESF instead refers to 'data-driven' DHTs, because this is a term that is easier to define in clear terms.

Company

Any commercial entity that is selling or planning to sell a 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 are 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.

Digital health technology

DHTs include standalone software and apps that are used to improve health outcomes or to improve how the health and care system runs. These can include:

- regulated medical devices classed as software as a medical device (SaMD) or AI as a medical device (AIaMD)
- software and apps designed to help people to manage their own health and wellbeing
- software that is designed to help the health and care system to run more efficiently or to help staff manage their time, staffing or resources
- apps or software designed to work alongside a medical device.

Software that is embedded in a physical medical device is excluded from this definition.

End user

Any person who 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 used generally. 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.

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