NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

EVIDENCE STANDARDS FRAMEWORK FOR DIGITAL HEALTH TECHNOLOGIES

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Evidence Standards Framework for Digital Health Technologies

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Evidence Standards Framework for Digital Health Technologies

Introduction

This document describes an evidence standards framework for digital health technologies (DHTs). It was developed by NICE between June 2018 and February 2019 in collaboration with NHS England, Public Health England and MedCity. The work was commissioned by NHS England.

The framework describes standards for the evidence that should be available, or developed, for DHTs to demonstrate their value in the UK health and care system. This includes evidence of effectiveness relevant to the intended use(s) of the technology and evidence of economic impact relative to the financial risk.

The evidence standards framework is intended to be used by technology developers to inform their evidence development plans, and by decision makers who are considering whether to commission a DHT.

Section A comprises evidence for effectiveness standards. Section B comprises evidence for economic impact standards.

NICE is grateful to the wide range of stakeholders who helped develop the concepts and content, and to those who provided comment and feedback on the initial version published in December 2018.

For further information, see the user guide.

Scope

The evidence standards framework is not suitable for all DHTs.

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

The framework may be used with DHTs that incorporate artificial intelligence using fixed algorithms. However, it is not designed for use with DHTs that incorporate artificial intelligence using adaptive algorithms (that is, algorithms which continually and automatically change). Separate standards (including principle 7 of the code of conduct for data-driven health and care technology) will apply to these DHTs.

Section A: Evidence for effectiveness standards

How to use these standards

- Choose the functional classification that best describes the main function of the DHT. For DHTs with more than 1 function, use the function in the highest applicable evidence tier.
- Use figure 1 and table 1 to identify into which evidence tier the DHT fits based on its functional classification. There is an evidence table associated with each evidence tier: see tables 3 to 6. The tables show 2 levels of evidence for the criteria in each tier: a minimum evidence standard and a best practice standard.
- Use the contextual questions to identify any potential specific risks associated with the DHT.
- Use the best practice standards for DHTs that present a higher potential risk within the tier. Use the minimum evidence standards for DHTs that do not present any specific risks.

The evidence tiers are **cumulative**. This means that a DHT must meet all the standards in the previous tier(s), as well as its own tier. For example, a DHT in tier 3a must meet the standards for tier 1, tier 2 and tier 3a; a DHT in tier 3b must meet the standards for tier 1, tier 2 and tier 3b. Where the contextual questions identify a specific risk, the best practice standard applies in all tiers.

The evidence standards framework is designed to be complementary to existing guidance and regulations on relevant standards for DHTs. Other relevant standards and regulations that may also need to be considered are listed in the accompanying user guide. The framework directly supports relevant principles, particularly principle 8, in the code of conduct for data-driven health and care technology.

NICE has also published resources to support this framework, including case studies which show the functional classification and evidence levels in use.

Functional classification of DHTs

Classifying DHTs by function (see figure 1) allows them to be stratified into evidence tiers based on the potential risk to users. The evidence level needed for each tier is proportionate to the potential risk to users presented by the DHTs in that tier.

The classification does not consider whether the DHT must be CE marked under the Medical Device Regulations. The evidence standards in tier 3b are intended to be complementary to the requirements for regulatory approval under the Medical Device Regulations.

Functional classification is intended to be a pragmatic approach to differentiating the main functions of the types of DHTs that are expected to be most widely developed and used in the UK health and care system.

Figure 1 DHTs classified by function and stratified into evidence tiers

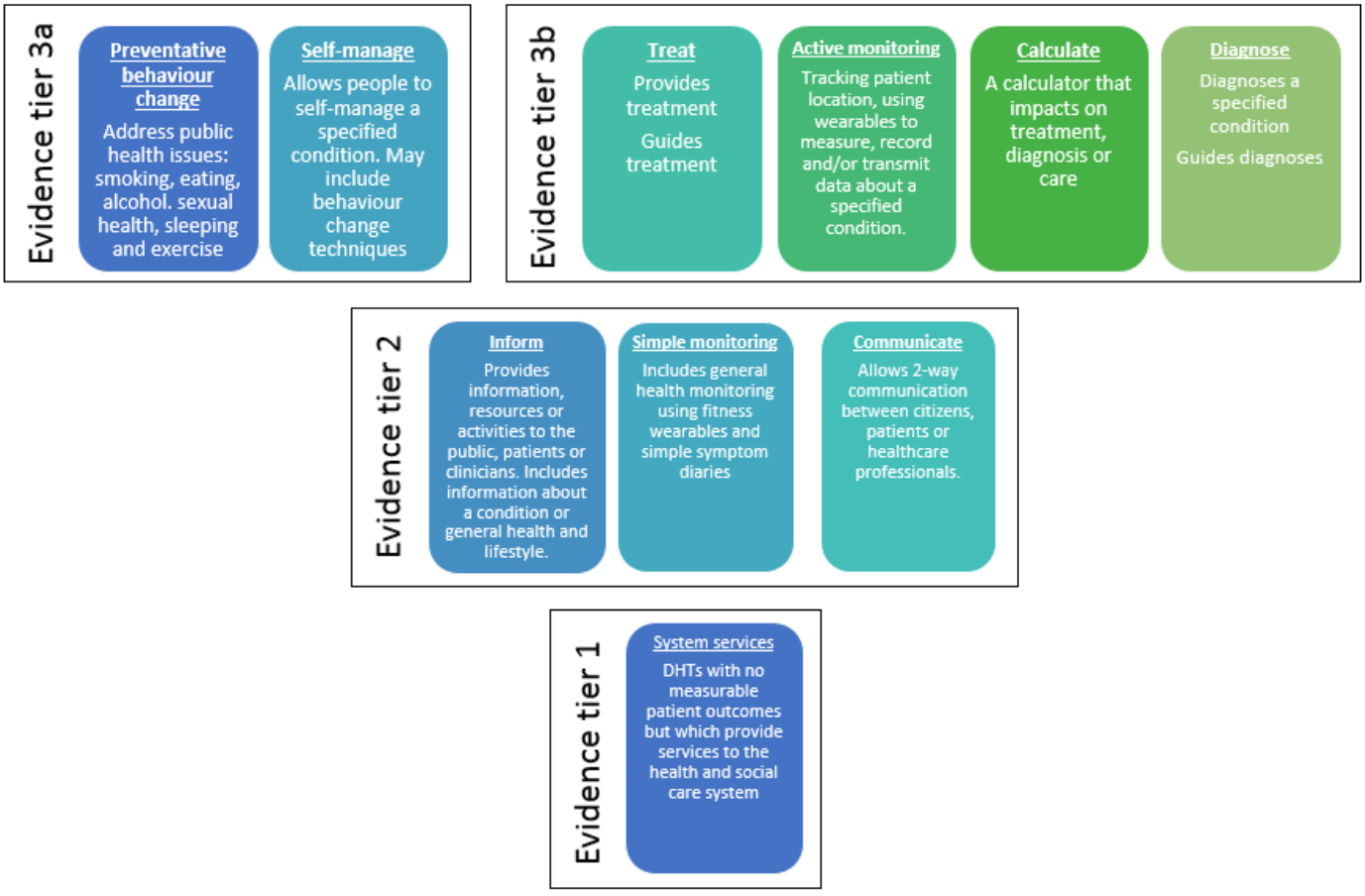


Table 1 describes the different functional classifications of DHTs in each tier. The examples are given for illustration and are not intended to be exhaustive.

Table 1 DHTs in each evidence tier after being stratified by functional classification

Evidence tier	Functional classification	Description	Includes (for example)	Excludes (for example)
Tier 1: DHTs with potential system benefits but no direct user benefits.	System service.	Improves system efficiency. Unlikely to have direct and measurable individual patient outcomes.	Electronic prescribing systems. Electronic health record platforms. Ward management systems.	Systems that provide treatment or diagnoses, such as early warning systems that monitor patient vital signs.
Tier 2: DHTs which help users to understand healthy living and illnesses but are unlikely to have measurable user outcomes.	Inform.	Provides information and resources to patients or the public. Can include information on specific conditions or about healthy living.	DHTs describing a condition and its treatment. Apps providing advice for healthy lifestyles (such as recipes). Apps that signpost to other services.	Tools that collect symptom data from users. Tools that provide treatment for a condition. Apps that allow communication among users, or between users and professionals.
	Simple monitoring.	Allows users to record health parameters to create health diaries. This information is not shared with or sent to others.	Health tracking information such as from fitness wearables. Symptom or mood diaries.	DHTs that share information with professionals, carers or other users. Tools that provide treatment for a condition.
	Communicate.	Allows 2-way communication between users and professionals, carers, third-party organisations or peers. Clinical advice is provided by a professional using the DHT, not by the DHT itself.	Instant messaging apps for health and social care. Video conference-style consultation software. Platforms for communication with carers or professionals.	DHTs that provide clinical content themselves (such as cognitive behavioural programmes for depression).

Tier 3a: DHTs for preventing and managing diseases. They may be used alongside treatment and will likely have measurable user benefits.	Preventative behaviour change.	Designed to change user behaviour related to health issues with, for example, smoking, eating, alcohol, sexual health, sleeping and exercise. Prescribed to users by a professional.	Smoking cessation DHTs and those used as part of weight loss programmes. DHTs marketed as aids to good sleep habits.	DHTs that describe themselves as a treatment for a diagnosed condition. Apps that provide general healthy lifestyle advice.
	Self-manage.	Aims to help people with a diagnosed condition to manage their health. May include symptom tracking function that connects with a healthcare professional.	DHTs that allow users to record, and optionally to send, data to a healthcare professional to improve management of their condition.	DHTs that describe themselves as a treatment for a diagnosed condition. Apps that automatically monitor and report data to a healthcare professional or third-party organisation.
Tier 3b: DHTs with measurable user benefits, including tools used for treatment and diagnosis, as well as those influencing clinical management through active monitoring or calculation. It is possible DHTs in this tier will qualify as medical devices.	Treat.	Provides treatment for a diagnosed condition (such as CBT for anxiety), or guides treatment decisions.	DHTs for treating mental health or other conditions. Clinician-facing apps that advise on treatments in certain situations.	Apps that provides general health advice or advice on living with a diagnosed condition. DHTs that offer general advice for clinicians such as online textbooks or digital versions of care pathways.
	Active monitoring.	Automatically records information and transmits the data to a professional, carer or third-party organisation, without any input from the user, to inform clinical management decisions.	DHTs linked to devices such as implants, sensors worn on the body or in the home. Data are automatically transmitted through the DHT for remote monitoring.	DHTs that allow a user to choose if and when to send recorded data to a professional, carer or third-party organisation.

	Calculate.	Tools that perform clinical calculations that are likely to affect clinical care decisions.	DHTs for use by clinicians, professionals or users to calculate parameters pertaining to care, such as early warning system software.	DHTs that diagnose or provide treatment for a condition.
	Diagnose.	Uses data to diagnose a condition in a patient, or to guide a diagnostic decision made by a healthcare professional.	DHTs that diagnose specified clinical conditions using clinical data.	DHTs that offer general lists of signs and symptoms for healthcare conditions.

Contextual questions to help identify higher-risk DHTs

The evidence tiers have been designed to broadly capture the level of clinical risk presented by DHT functional groups. However, even within a functional group, different DHTs may present specific risks based on their intended use. These contextual questions may be useful to help identify potentially higher-risk DHTs. Best practice evidence standards in each relevant evidence tier should be used for DHTs that present a potential high risk.

Table 2 Contextual questions to help identify higher-risk DHTs

Question	Risk adjustment
Are the intended users of the DHT considered to be in a potentially vulnerable group such as children or at-risk adults?	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.' If the DHT is intended to be used by people considered to be in a potentially vulnerable group then a higher level of evidence may be needed, or relevant expert opinion on whether the needs of the users are being appropriately addressed.
How serious could the consequences be to the user if the DHT failed to perform as described?	A higher level of potential harm may indicate that the best practice evidence standards should be used.
Is the DHT intended to be used with regular support from a suitably qualified and experienced health or social care professional?	DHTs that are intended to be used with support (that is, with regular support or guidance from a suitably qualified and experienced health or social care professional) could be considered to have lower risk than DHTs that are intended to be used by the patient on their own. *This contextual question may require careful interpretation depending on the individual DHT as the involvement of a clinician may in itself indicate that the DHT presents a specific risk.*
Does the DHT include machine learning algorithms or artificial intelligence?	Refer to the code of conduct for data-driven health and care technology for additional considerations when assessing DHTs that use artificial intelligence or machine learning.

Is the financial or organisational risk of the DHT expected to be very high?	DHTs with very high financial risk should be assessed using the best practice standards to provide surety that the DHT represents good value. High organisational risks may include situations in which implementing the DHT would need complex changes in working practice or care pathways.

Evidence for effectiveness tables

About the evidence tables

Each table corresponds to an evidence tier:

- Tier 1 evidence for effectiveness standards: table 3
- Tier 2 evidence for effectiveness standards: table 4
- Tier 3a evidence for effectiveness standards: table 5
- Tier 3b evidence for effectiveness standards: table 6

The evidence tiers are **cumulative**. This means that a DHT must meet all the standards in the previous tier(s), as well as its own tier.

The tables show 2 levels of evidence for the criteria in each tier: a minimum evidence standard and a best practice standard.

For more information, see how to use these standards.

Tier 1 evidence for effectiveness standards

Tier 1 evidence standards apply to DHTs which are functionally classified as system services.

Table 3 Evidence for effectiveness standards for tier 1 DHTs

Evidence category	Minimum evidence standard	Best practice standard
Credibility with UK health and social care professionals.	Be able to show that the DHT has a plausible mode of action that is viewed as useful and relevant by professional experts or expert groups in the relevant field. Either: • show that relevant clinical or social care professionals working within the UK health and social care system have been involved in the design, development or testing of the DHT, or • show that relevant clinical or social care professionals working within the UK health and social care system have been involved in signing-off the DHT, indicating their informed approval of the DHT.	Published or publicly available evidence documenting the role of relevant UK health or social care experts in the design, development, testing or sign-off of the DHT.
Relevance to current care pathways in the UK health and social care system.	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 care pathways and service provision in the UK. Also evidence that the DHT is able to perform its intended function to the scale needed (for example, having servers that can scale to manage the expected number of users).	Evidence to show successful implementation of the DHT in the UK health and social care system.
Acceptability with users.	Be able to show that representatives from intended user groups were involved in the design, development or testing of the DHT. Provide data to show user satisfaction with the DHT.	Published or publically available evidence to show that representatives from intended user groups were involved in the design, development or testing of the DHT and to show that users are satisfied with the DHT.

Equalities considerations.	Evidence, if relevant, 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. • Contribute to promoting equality, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (as described in the 2010 Equalities Act) and others.	Show evidence of the DHT being used in hard-to-reach populations.
Accurate and reliable measurements (if relevant).	Data or analysis which shows that the data generated or recorded by the DHT is: • accurate • reproducible • relevant to the range of values expected in the target population. Also data showing that the DHT is able to detect clinically relevant changes or responses.	As for the minimum evidence standard.
Accurate and reliable transmission of data (if relevant).	Technical data showing that numerical, text, audio, image-based, graphic-based or video information is: • not changed during the transmission process • not biased by the data 'value' expected from the target patient population.	As for the minimum evidence standard, but with quantitative data.

Tier 2 evidence for effectiveness standards

Tier 2 evidence standards apply to DHTs which provide information, simple monitoring functions or communication platforms. **DHTs in tier 2 must also meet the standards in tier 1.**

Table 4 Evidence for effectiveness standards for tier 2 DHTs

Evidence category	Minimum evidence standard	Best practice standard
Reliable information content.	Be able to show that any health information provided by the DHT is: • 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 • up to date • reviewed and updated by relevant experts at defined intervals, such as every year • sufficiently comprehensive.	Evidence of endorsement, accreditation or recommendation by NICE, NHS England, a relevant professional body or recognised UK patient organisation. Alternatively, evidence that the information content has been validated though an independent accreditation such as The Information Standard or HONcode certification.
Ongoing data collection to show usage of the DHT.	Commitment to ongoing data collection to show **usage** of the DHT in the target population, and commitment to share, when available, with relevant decision-makers such as commissioners in a clear and useful format.	Evidence that data on **usage** is being collected in line with the minimum standards and can be made available to relevant decision-makers.
Ongoing data collection to show value of the DHT.	Commitment to ongoing data collection to show **user outcomes** (if relevant) or **user satisfaction** (using non-patient identifiable information) to show ongoing value, and commitment to share, when available, with relevant decision-makers such as commissioners in a clear and useful format.	Evidence that data on **outcomes or user satisfaction** is being collected in line with the minimum standard and can be made available to relevant decision-makers.
Quality and safeguarding.	Show that appropriate safeguarding measures are in place around peer-support and other communication functions within the platform. 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 in peer-to-peer communication, for example through user agreements or moderation.	As for the minimum evidence standard.

Tier 3a evidence for effectiveness standards

Tier 3a evidence standards apply to DHTs for preventative behaviour change, or which allow self-management of a diagnosed condition. **DHTs in tier 3a must also meet the standards in tiers 1 and 2.**

Table 5: Evidence for effectiveness standards for tier 3a DHTs

Evidence category	Minimum evidence standard	Best practice standard
Demonstrating effectiveness.	High quality observational or quasi-experimental studies demonstrating relevant outcomes. These studies should present comparative data. Comparisons could include: • relevant outcomes in a control group • use of historical controls • routinely collected data. Relevant outcomes may include: • behavioural or condition-related user outcomes such as reduction in smoking or improvement in condition management • evidence of positive behaviour change • user satisfaction.	High quality intervention study (quasi-experimental or experimental design) which incorporates a comparison group, showing improvements in relevant outcomes, such as: • patient-reported outcomes (preferably using validated tools) including symptom severity or quality of life • other clinical measures of disease severity or disability • healthy behaviours • physiological measures • user satisfaction and engagement • health and social care resource use, such as admissions or appointments. The comparator should be a care option that is reflective of standard care in the current care pathway, such as a commonly used active intervention.
Use of appropriate behaviour change techniques (if relevant).	Be able to show that the techniques used in the DHT are: • consistent with recognised behaviour change theory and recommended practice (aligned to guidance from NICE or relevant professional organisations) • appropriate for the target population.	Published qualitative or quantitative evidence showing that the techniques used in the DHT are: • based on published and recognised effective behaviour change techniques • aligned with recommended practice • appropriate for the target population.

Tier 3b evidence for effectiveness standards

Tier 3b evidence standards apply to DHTs that are designed to provide or guide treatment, active monitoring and clinical calculations, or provide or guide a diagnosis. **Tier 3b DHTs must also meet the standards in tiers 1 and 2.**

Table 6 Evidence for effectiveness standards for tier 3b DHTs

Evidence category	Minimum evidence standard	Best practice standard
Demonstrating effectiveness.	High quality intervention study (experimental or quasi-experimental design) showing improvements in relevant outcomes, such as: • diagnostic accuracy • patient-reported outcomes (preferably using validated tools) including symptom severity or quality of life • other clinical measures of disease severity or disability • healthy behaviours • physiological measures • user satisfaction and engagement. Generic outcome measures may also be useful when reported alongside condition-specific outcomes. The comparator should be a care option that is reflective of the current care pathway, such as a commonly used active intervention.	High quality randomised controlled study or studies done in a setting relevant to the UK health and social care system, comparing the DHT with a relevant comparator and demonstrating consistent benefit including in clinical outcomes in the target population, using validated condition-specific outcome measures. Alternatively, a well-conducted meta-analysis of randomised controlled studies if there are enough available studies on the DHT.

More information on the evidence for effectiveness standards

This section provides more information about how each evidence for effectiveness standard may be met.

Credibility with UK health and social care professionals (tier 1)

This standard is intended to show that the DHT has a plausible mode of action and reflects current standard/best practice in the UK health and social care system, or provides an alternative to standard/best practice that is beneficial to users and the health and social care system.

Evidence may include a report signed by a named expert or experts, documenting their role in the design, development, testing or sign-off of the DHT.

Relevance to current care pathways in the UK health and social care system (tier 1)

Meeting this standard shows that the DHT is relevant to the UK health and social care system. For the minimum evidence standard, evidence could include published or unpublished reports describing a successful trial of the DHT in a relevant UK setting showing benefit to users. The report should include a description of the DHT's effect on the care pathway as well as any recorded user and resource benefits. For the best practice standard, evidence could include published or unpublished reports describing the successful implementation of the DHT showing benefits to users in the UK health and social care system.

Acceptability with users (tier 1)

Some evidence to show that potential users of the DHT have tested it and found it to be usable and useful will help to show that implementing the DHT may be successful. Evidence could include reports from user or user group testing, or showing that users have been consulted in the design and development process.

Equalities considerations (tier 1)

Consider whether the DHT helps to reduce any existing inequalities within the health and social care system. This could include factors such as digital exclusion, or use by hard-to-reach populations.

Indicate any equalities considerations needed when commissioning, adopting or implementing the DHT, particularly in reference to the Equality Act 2010.

Reliable information content (tier 2)

Any information or advice to users concerning health, healthy living, lifestyle, diseases, illnesses or conditions must be correct and relevant.

Ongoing data collection to show usage of the DHT (tier 2)

To ensure value for money to the health and social care system, the DHT owner must commit to providing data showing that the DHT is used as expected by the intended user group after adoption. The DHT owner should define in advance the format and schedule for data reporting with, for example, commissioners.

Ongoing data collection to show value of the DHT (tier 2)

To ensure value for money to the health and social care system, the DHT owner must commit to providing data demonstrating that people using the DHT are showing the expected benefits from its use. This could include improvements in symptoms or general health measures. The DHT owner should agree the format and schedule for data reporting with the commissioner.

Quality and safeguarding (tier 2)

Some DHTs provide chat platforms or peer-to-peer communication, or link the user to support from third-party organisations. The DHT owner should be able to clearly identify who the user can interact with, describe why these interactions are appropriate, any risks in those interactions, and what safeguarding measures have been put in place.

Demonstrating effectiveness (tier 3a, minimum evidence standard)

A high quality observational or quasi-experimental study would observe and clearly describe the effect of the DHT on a group of representative users, and allow some comparison with outcomes without the intervention. The study would include statistical considerations such as sample size and statistical testing, report outcomes (ideally valid and reliable outcome measures) that are relevant to the condition, and be clear on reporting the outcomes of every person in the trial.

Demonstrating effectiveness (tier 3a, best practice standard)

A high quality intervention study using a quasi-experimental or experimental design would compare the effect of the DHT on a group of users with 1 or more groups having a different (or no) intervention. The study would report the difference between the groups. It would include statistical considerations such as sample size and statistical testing, report outcomes that are relevant to the condition, and be clear on reporting the outcomes of every person in the group testing the DHT. Ideally, the comparator group would be people having current standard care, but it could also be a before-and-after study (measuring people's symptoms over a period of time before they use the DHT then comparing this with while they are using the DHT).

Use of appropriate behaviour change techniques (tier 3a)

DHTs that aim to change the behaviour of the users should be consistent with accepted and effective behaviour change techniques. The DHT owner should be able to describe which behaviour change techniques are used and provide references to these.

Demonstrating effectiveness (tier 3b, minimum evidence standard)

A high quality intervention study using a quasi-experimental or experimental design would compare the effect of the DHT on a group of users with 1 or more groups having a different (or no) intervention. The study would report the difference between the 2 groups. The study would include statistical considerations such as sample size and statistical testing, report outcomes that are relevant to the condition, and be clear on reporting the outcomes of every person in the group testing the DHT. Ideally, the comparator group would be people having current standard care, but could also be a before-and-after study (measuring people's symptoms over a period

of time before they use the DHT then comparing this with while they are using the DHT).

The outcome measures reported should reflect best practice for reporting improvements in the specific condition, using validated outcome measures such as those in the COMET core outcome set.

Demonstrating effectiveness (tier 3b, best practice standard)

A high quality randomised controlled trial or trials would take a group of people with the condition and randomly assign people to use the DHT or a comparator. The people in both groups would be followed-up over a relevant period of time to compare the outcomes of the groups.

The study would report the difference between the 2 groups. The study would include statistical considerations such as sample size and statistical testing, report outcomes that are relevant to the condition, and be clear on reporting the outcomes of every person in the group testing the DHT. The improvements measured should be clinically relevant.

Ideally, the comparator group would be people having current standard care, but comparative outcomes could also be collected in a before-and-after study (measuring people's symptoms over a period of time before they use the DHT then comparing this with while they are using the DHT).

The outcome measures reported should reflect best practice for reporting improvements in the specific condition, using validated outcome measures such as those in the COMET core outcome set.

Section B: Evidence for economic impact standards

How to use these standards

The evidence for economic impact standards are based on our current understanding of the digital healthcare field and NICE's experience in evaluating other medical technologies such as devices and diagnostics.

The economic impact standards aim to promote a consistent and streamlined pathway for economic assessment of DHTs. They are designed to help developers and others understand what information is needed for an effective economic analysis, with the ultimate aim of increasing the capacity for economic analysis across the wider innovation landscape. A better understanding of economic impact should result in more accurate business cases and increasing confidence in investing in DHTs. The standards support the aims of principle 2 in the code of conduct for data-driven health and care technology.

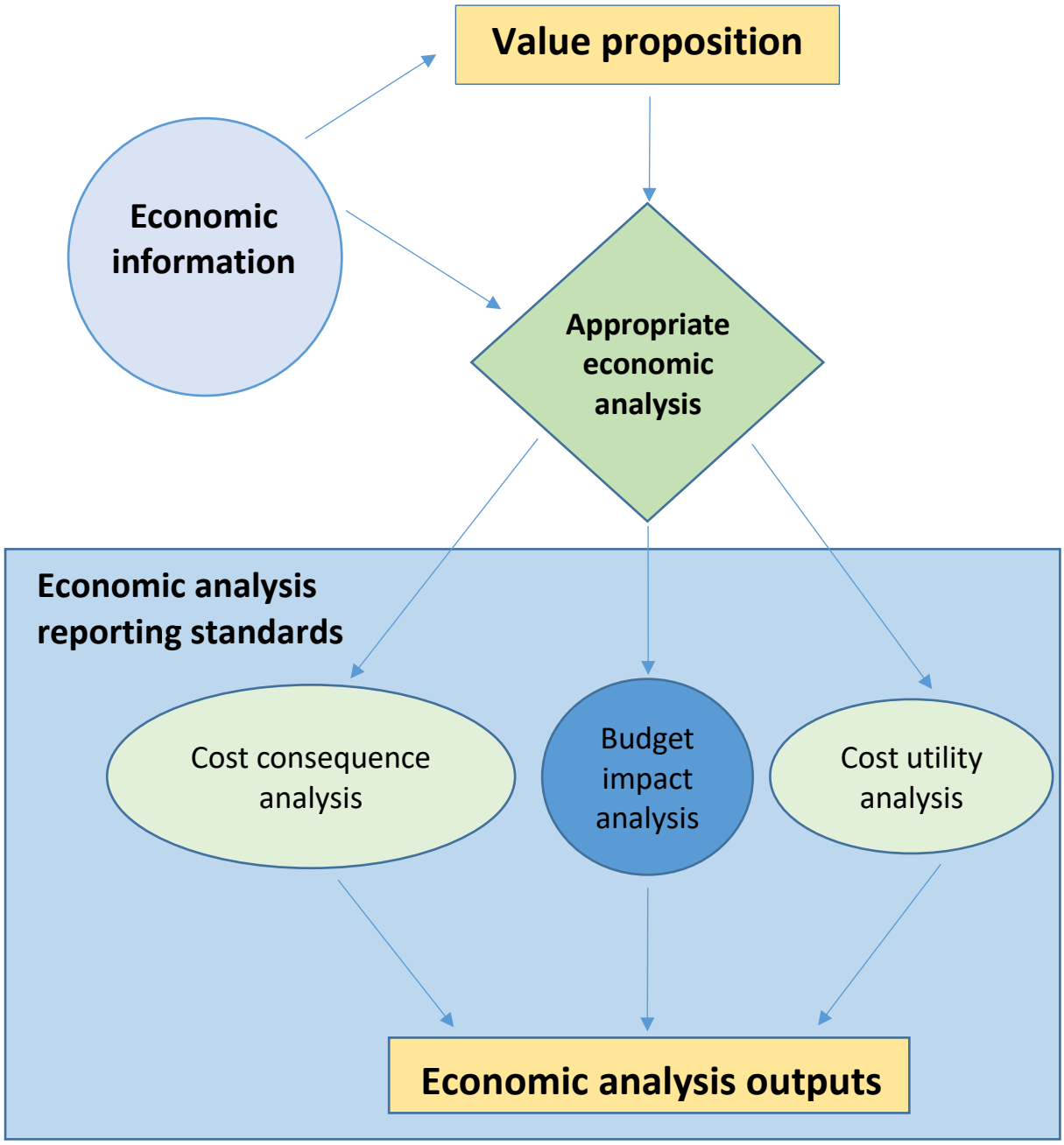
The evidence for economic impact standards are separated into 3 components:

- key economic information (table 7)
- appropriate economic analysis (table 8 and table 9)
- economic analysis reporting standards (table 10).

Figure 2 illustrates how the economic impact standard components come together to produce economic analysis outputs and also relate to the value proposition referred to in principle 2 of the code of conduct for data-driven health and care technology. Applying these standards when evaluating DHTs should produce reliable and robust information about the economic impact of adopting a technology.

For more information, see the user guide.

Figure 2. Overview showing the relationship between components of evidence standards for economic impact



Evidence for economic impact standards

Key economic information

In order to assess the economic impact of a DHT, the costs and benefits of the intervention should be compared with existing practice. To do this, key economic information (table 7) must be collected and used to populate an economic model. This information should comprise:

- user population size
- current and proposed care pathways
- parameters for the economic model.

A hierarchy of data sources for parameters in economic analyses is presented in table 4 (page 56) of the NICE Decision Support Unit document identifying and reviewing evidence to inform the conceptualisation and population of cost-effectiveness models (TSD13).

Table 7 Evidence for economic impact standards: key economic information

Key economic information	Component	Standard
User population size.	N/A.	Describe the user population, its size, the expected uptake and the sources for each of these. Note any subgroups with different expected uptake rates and how these may change over time. Demonstrate that the user population size is: • calculated using appropriate and current national or local sources for the target population (for example, accurate epidemiological data of prevalence and incidence of the relevant health problem), or expert estimates if this is not available • calculated using uptake rates from pilot data or other usage data from the developer • validated as a fair representation of what is expected (including any variations by subgroup and over time) by showing approval and support from relevant professionals in the UK health and social care system. Note that NICE's resource impact assessment manuals describe an approach to calculating population size.
Care pathways.	Existing pathway.	Describe the steps in the current care pathway for the relevant population and setting. Use national clinical guidelines, national guidance or academic literature and consultation with healthcare professionals and patients to map out the existing care pathway. If there is no existing care pathway, the impact of adopting the technology should be clearly specified using an approach which can be used as a basis for an economic model. In some cases there may be multiple existing care pathways, each of which should be fully described. Show that the existing care pathway: • is mapped in a comprehensive, detailed and stepwise approach (for example, using a flow chart). • is validated as an accurate representation of current care (that is, it is the most commonly used active intervention) by relevant professionals in the UK health and social care system.
	Proposed pathway.	Describe the steps in the proposed new care pathway or pathways incorporating the DHT intervention for the relevant population and setting. Detail any infrastructure and service-level changes needed to existing

		pathways and associated systems to implement, operate and maintain the new pathway. Describe any influential contextual issues that may act as barriers or enablers to implementation.
Parameters for the economic model.	Intervention parameters (health and other outcomes from intended use).	Describe the health and other outcomes associated with using the DHT and in current practice. If possible, quantify the uncertainty associated with parameters (for example, with confidence intervals or probability distribution). The best quality evidence available for the impact of the interventions should be used. Sources for health and other outcomes should be as described in the relevant tier of the evidence for effectiveness standards. Evidence syntheses may be needed if there is more than 1 relevant data source. More robust estimates will be needed for higher financial risk interventions.
	Cost parameters.	Show that the cost parameters are informed by costs relevant to a health and social care decision-maker. Suitable sources include NHS reference costs or national tariffs. All costs associated with the interventions should be considered
	Resource use parameters.	Show that the resource use parameters are based on study, pilot or real-world usage data, or on information obtained from relevant clinical or social care professionals or other appropriate sources. Show that the resource use parameters for the existing care pathway are validated as an accurate and comprehensive itemisation of resources currently used (including any variations by subgroup and over time) by evidencing approval and support from relevant professionals in the UK health and social care system. Show that the resource use parameters for the new care pathway are validated as an accurate and comprehensive itemisation of resources necessary and expected to be used in the new care pathway (including any variations by subgroup and over time) by evidencing approval and support from relevant professionals in the UK health and social care system.
	Utilities (when a cost-utility analysis is appropriate).	Show that utility data are measured using an appropriate standard measure, such as the EQ-5D. A rationale for the choice of measure should be provided. Show that the data has been collected in an appropriate way.

Appropriate economic analysis

The economic impact of a DHT can be assessed using an appropriate analysis of the economic information collected. The type of economic analysis done should be determined by the financial consequences of adopting and implementing the DHT from a payer or commissioner perspective. The appropriate level of economic analysis depends on the type of decision needed and likely financial commitment. To reflect the range of commissioning decisions associated with DHTs, we have proposed 3 levels of economic analysis (see table 8).

Many DHTs will start at a basic economic analysis level but, with additional information and data about the technology and its comparators, a more robust economic analysis can be undertaken. The higher levels of economic analysis needed depends on the financial commitment required including, for example, the level of upfront investment, the likelihood of opportunity costs and the certainty of the realisation of the benefits. Factors which influence the level of economic analysis include:

- stage in the lifecycle of the DHT
- the value proposition of the DHT
- strength and quality of the evidence for effectiveness
- strength and quality of the evidence for economic impact
- potential financial and organisational impact of the DHT (for example, likelihood of opportunity costs and reorganisation or disruption to existing services)
- total cost to the payer for the estimated user population for the proposed length of use (including the upfront cost of the DHT and implementation, training, operation and maintenance costs).

Table 8 Economic impact standards: levels of economic analysis

Typical commissioning decision	Typical level of economic risk to the payer	Economic analysis level
Pilot study or local commissioning decision.	Low.	Basic.
Local or regional commissioning and national commissioning for cost-saving DHTs.	Medium (for example, significant implementation costs but the DHT is expected to save money overall).	Low financial commitment.
National commissioning for cost-incurring DHTs.	High (for example, service redesign costs).	High financial commitment.

An economic analysis will be needed for all DHTs to assess the financial impact of their adoption. Table 9 describes the types of economic analyses associated with the different levels.

Table 9 Evidence for economic impact standards: appropriate economic analysis

Economic analysis level	Appropriate economic analysis	Outputs
Basic.	Budget impact analysis.	Estimated yearly budget impact for years 1 to 2. Data may be collected to inform future economic analyses.
Low financial commitment.	Cost-consequence analysis.	Estimated costs and benefits. Sensitivity analysis results.
	Budget impact analysis.	Estimated yearly budget impact for years 1 to 5. Sensitivity analysis results.
High financial commitment.	For DHTs with health outcomes funded by the NHS and Personal Social Services, a cost-utility analysis should be done using NICE's guide to the methods of technology appraisal as a reference case.	Estimated incremental cost-effectiveness ratio. Sensitivity analysis results.
	For DHTs funded by the public sector with health and non-health outcomes, or for DHTs that focus on social care, a cost-utility analysis should be done. If this is not possible, a cost-consequence analysis may be acceptable. The analysis should be done using developing NICE guidelines: the manual as a reference case.	Estimated incremental cost-effectiveness ratio (cost-utility analysis) or estimated costs and benefits (cost-consequence analysis). Sensitivity analysis results.
	Budget impact analysis.	Estimated yearly budget impact for years 1 to 5. Sensitivity analysis results.

At the basic level of economic analysis, for DHTs with a less mature evidence base, a budget impact analysis should be done.

For technologies which represent a low financial commitment from a payer perspective, a cost-consequence analysis should be done. This allows the exploration of whether differences in expected costs between options can be justified in terms of expected benefits (for example, effectiveness outcomes). It is expected that there will be sensitivity analysis to explore the uncertainties in the model. The results can be used to inform a budget impact analysis. This approach aligns decisions on these DHTs with cost-saving medical devices and diagnostics considered by the medical technologies evaluation programme at NICE.

For technologies which present a high financial commitment from a payer perspective, a cost-utility analysis should be done. A cost-utility analysis allows the exploration of whether differences in expected costs between options can be justified in terms of expected health effects measured in quality-adjusted life years. For some high financial commitment DHTs with non-health outcomes, a cost-utility analysis may not be possible and instead a cost-consequence analysis may be used. This approach aligns decisions on these DHTs with other technologies considered by NICE in its guidelines and technology appraisal programmes. The results, including can be used to inform a budget impact analysis.

Economic models should be developed following a systematic, transparent and justifiable process similar to that described in the NICE Decision Support Unit document identifying and reviewing evidence to inform the conceptualisation and population of cost-effectiveness models (TSD13).

NICE has developed a template which can be used for a budget impact analysis. This is a standalone Excel file which can be populated with the appropriate economic information. It is an optional tool that has been designed for use by developers or commissioners to analyse the economic impact of some DHTs. It will not be suitable for all DHTs. The template is supported by a guide which explains the concepts behind a cost-consequence analysis and a budget impact analysis.

Economic analysis reporting standards

These reporting standards are adapted from the reference case used in NICE's guide to the methods of technology appraisal and the Consolidated Health Economic Evaluation Reporting Standards (CHEERS). Each component should be considered from the outset of designing the economic analysis and reported alongside the findings.

Table 10 Evidence for economic impact standards: economic analysis reporting

Component	Standards
Economic perspective	Describe and justify and provide rationale for the perspective used. This should be that of the decision maker or payer (that is, from a UK health and social care system perspective or societal perspective if local authority or public health decision maker).
Time horizon	Describe and justify the time horizon used. This should be long enough to capture all costs and to account for all health outcomes.
Discounting	Describe and justify whether discounting was used. Discounting can be applied to costs and savings that occur after the initial year using standard UK Treasury recommendations.
Sensitivity analyses	Describe and justify the sensitivity analyses used. Present the results of the sensitivity analyses clearly depicting the main parameters and assumptions that have the largest effect.
Equity analysis	If there are good clinical data to show that the effects differ by demographic factors, include subgroup analyses to show the relevant economic impact.
Descriptions of any additional analytical methods	Describe any analytical methods involved in the economic analysis such as methods for synthesising data from different sources, extrapolating, validating or adjusting data and approaches to using skewed, missing, censored, heterogeneous or uncertain data.
Critique of the economic analysis	Present the strengths and weaknesses of the economic analysis and its generalisability to the local context.

Glossary

Artificial intelligence	Artificial intelligence (AI) is an area of computer science that makes it possible for 'machines' to learn from new experiences, adjust outputs and perform human-like tasks. It is generally classified into: • Narrow AI, which focuses on a specific task, or works within a narrow set of parameters such as reading radiology scans or optimising hospital workflows. • Strong or general AI, which refers to AI that can learn to do several different tasks. AI can incorporate algorithms that do not automatically change over time (fixed algorithms) or algorithms that are automatically and continually updated (adaptive algorithms). Definition from The AHSN Network Accelerating Artificial Intelligence in health and care: results from a state of the nation survey.
Budget impact analysis	Analysis of the financial change in the use of resources (cost or saving) as a result of implementing a technology. The budget impact is determined by estimating costs and savings as a direct consequence of implementing the guidance. Direct consequences are the changes in practice that will result from implementation. See the NICE Assessing resource impact process manual: technology appraisals and highly specialised technologies for further details.
Cost-consequence analysis	One of the tools used to carry out an economic evaluation. This compares the costs (such as treatment and hospital care) and the consequences (such as health outcomes) of a test or treatment with a suitable alternative. Unlike cost-benefit analysis or cost-effectiveness analysis, it does not attempt to summarise outcomes in a single measure (such as the quality-adjusted life year) or in financial terms. Instead, outcomes are shown in their natural units (some of which may be monetary) and it is left to decision-makers to determine whether, overall, the treatment is worth carrying out.
Cost-utility analysis	One of the tools used to carry out an economic evaluation. The benefits are assessed in terms of both quality and duration of life, and expressed as quality-adjusted life years (QALYs). See also Utility.
Digital health technologies	Apps, programmes and software used in the health and care system. They may be standalone or combined with other products such as medical devices or diagnostic tests.
Digital assessment questions (DAQ)	The Digital Assessment Questions (DAQ) is a self-certification tool that includes questions on clinical safety, data protection, security, usability and accessibility, interoperability and technical stability. The DAQ is aligned with the requirements of the General Data Protection Regulation (GDPR). The DAQ is used to assess all products featured in the NHS Apps Library. Further information can be found at the Health Developer Network.
Discounting	Costs and perhaps benefits incurred today have a higher value than costs and benefits occurring in the future. Discounting health benefits reflects individual preference for benefits to be experienced in the present rather than the future. Discounting

	costs reflects individual preference for costs to be experienced in the future rather than the present.
Economic analysis	Study or analysis of the cost of using and distributing health or social care resources.
EQ-5D	A standardised 5-dimensional instrument used to measure health outcomes. It is completed by the person having a treatment themselves and is quick to use.
Experimental study	See Intervention study.
Incremental cost-effectiveness ratio (ICER)	The difference in the change in mean costs in the population of interest divided by the difference in the change in mean outcomes in the population of interest.
Intervention study	In an intervention study the researcher selects a group of participants who are given an intervention under controlled conditions and makes some comparison of outcome measures from this group. This is either against a parallel control group of participants who do not receive the intervention, or against measures taken from the same group of participants when not receiving the intervention (for example, in a crossover or before-and-after study design). In an experimental intervention design the participants who receive the intervention is random; in a quasi-experimental design, the assignment is not random.
Machine learning	Machine learning is an application of artificial intelligence that provides systems the ability to automatically learn and improve from experience without being explicitly programmed. Machine learning focuses on the development of computer programs that can access data and use it learn for themselves.
Observational study	A retrospective or prospective study in which the investigator observes the natural course of events with or without control groups (for example, cohort studies and case–control studies).
Quasi-experimental study	See Intervention study.
Randomised controlled study	A study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug, treatment or other intervention. One group (the experimental group) has the intervention being tested, the other (the comparison or control group) has an alternative intervention, a dummy intervention (placebo) or no intervention at all. The groups are followed up to see how effective the experimental intervention was. Outcomes are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce bias.
Real-world data (RWD)	An umbrella term for data regarding the effects of health interventions (for example, safety, effectiveness, resource use, etc) that are not collected in the context of highly-controlled RCT's. Instead, RWD can either be primary research data collected in a manner which reflects how interventions would be used in routine clinical practice or secondary research data derived from routinely collected data. Data collected include, but are not limited to, clinical and economic outcomes, patient-reported outcomes (PRO) and health-related quality of life (HRQoL). RWD can be obtained from many sources including patient registries, electronic medical records, and claims databases. Definition from imi GetReal glossary.

Sensitivity analysis	A means of exploring uncertainty in the results of economic evaluations. There may be uncertainty because data are missing, estimates are imprecise or there is controversy about methodology. Sensitivity analysis can also be used to see how applicable results are to other settings. The analysis is repeated using different assumptions to examine the effect of these assumptions on the results.
Time horizon	The time period over which the main differences between interventions in effects and the use of resources in health and social care are expected to be experienced, taking into account the limitations of the supporting evidence.
Utility	In health economics, a 'utility' is the measure of the preference or value that an individual or society gives a particular health state. It is generally a number between 0 (representing death) and 1 (perfect health). The most widely used measure of benefit in cost-utility analysis is the quality-adjusted life year, which combines quality of life with length of life. Other measures include disability-adjusted life years (DALYs) and healthy year equivalents (HYEs).