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A Specification to Design a 'Consolidated Evaluation Framework for Technology Enabled Care'

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Glossary

AHSNs	Academic Health Science Networks
AI	Artificial Intelligence
BIA	Budget Impact Assessment
CAT	Complexity Assessment Toolkit
CBA	Cost-Benefit Analysis
CEFTEC	Consolidated Evaluation Framework for Technology Enabled Care
CFIR	Consolidated Framework for Implementation Research
DHI	Digital Health Innovation
DHT	Digital Health Technology
DTAC	Digital Technology Assessment Criteria for health and social care
ESF	Evidence Standards Framework
HINs	Health Innovation Networks (Formerly AHSNs)
HTA	Health Technology Assessment
ICB	Integrated Care Board
ICBT	Internet-Delivered Cognitive Behavior Therapy
IRIHS	Interdisciplinary Research in Health Sciences: University of Oxford
MALT	Mainstreaming Assisted Living Technologies
MHRA	Medicines and Healthcare products Regulatory Agency
NASSS	Nonadoption, Abandonment, Scale-Up, Spread, And Sustainability
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
ORCHA	The Organisation for the Review of Care and Health Apps
PARiHS	Promoting Action on Research Implementation in Health Services
PRINCE2®	PRojects IN Controlled Environments: project management training
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance Framework
SOCRATES	The SOcial Care Rapid evAluation Team (London School of Economics and Political Science, the University of Central Lancashire and King's College London)
TAM	Technology Acceptance Model
TEC	Technology Enabled Care
TEC AA	Technology Enabled Care Action Alliance
T-CaST	Theory, Model, and Framework Comparison and Selection Tool
TMFs	Theories, Models and Frameworks
WPs	Work-Packages
Y&H	Yorkshire and Humber

Executive Summary

Background

This document sets out the requirements for developing a universally accessible and comprehensive framework for evaluating technology enabled care (TEC). It describes 1) the current situation, 2) how current evidence might be applied immediately and 3) work required to develop an evaluation framework that is more appropriate for TEC. It is recognised that different types of information are required for different people in different circumstances.

Much of the evidence for TEC is derived from heterogeneous, short-term and small-scale pilot projects, which are often not sustained. We are lacking a consolidated approach to evaluation, which enables the aggregation of good quality evidence, aimed at supporting key decision-makers. However, there is potential for evidence gaps to be addressed by the development and application of a 'Consolidated Evaluation Framework for Technology Enabled Care'

Methods

We searched literature sources to capture existing evaluation theories, models, frameworks and taxonomies. These were critically reviewed to describe their strengths and weaknesses. The evidence was synthesised to consider the appropriateness of the available evaluation frameworks for providing or informing a comprehensive framework to evaluate technology enabled care.

In particular, it was noted that two consolidated frameworks are well-known and designed for universal application to evaluate digital health and care technologies (NICE ESF & NASSS framework). As these were closest to the specification requirements and (to an extent) designed for care technologies, they were scrutinised in greater detail.

Secondary outputs are an annotated bibliography of relevant literature and a live directory of Theories, Models and Frameworks (TMFs). The main outputs are 1) a 5-part framework specification for immediate use, which is formed from existing tools and guidance and 2) outline criteria and summary of work required for the design of a tailored 'Consolidated Evaluation Framework for Technology Enabled Care' (CEFTEC), which accounts for and incorporates important current knowledge and practice.

Findings

The evaluation landscape includes around 137 different theories, models, frameworks (TMFs) and approaches. Many with foundations in implementation science. Individual evaluation TMFs are for specific purposes and adopt various perspectives. Therefore, they are not useful for generic use.

For an informative evaluation, it is necessary to incorporate a wide range of behavioural theories and outcome patterns to describe what works, for whom, in what circumstances and why. Therefore, to have widespread application, evaluation frameworks usually combine various relevant TMFs (bespoke for each evaluation or using consolidated frameworks).

There seems to be a divide between approaches used by academics/evaluators and other practitioners. Whilst frameworks used by researchers and evaluators tend to be rigorously based on a wide range of evidence from previous research and can require extensive knowledge and experience to use, service providers, commissioners and developers tend to use simpler approaches such as the quadruple aim (i.e based on four dimensions of care: user outcomes, user experience, cost, and staff experience).

Rouleau et al (2023) suggest that, in the absence of a comprehensive framework it would be useful to share, compare and combine the main insights from evaluations as short, descriptive practical use cases (see appendix for example).

NICE ESF: The NICE Evidence Standards Framework (ESF) could be a promising starting point for the development of a framework. However, TEC does not map well onto the 3 DHT (Digital Health Technology) tiers of the NICE ESF. Additionally, the NICE ESF is weak on implementation, context, theory, adoption and spread.

NASSS: The NASSS framework encourages consideration of complexity to identify barriers to adoption, sustainability and spread. Owing to complexity, many digital health and care implementation projects fail. The NASSS can help provide data about why and how they fail. Whilst it is well-known, it is not clear to what extent the framework is used by academic researchers and evaluators or by developers, providers and commissioners. There are four different tools available to assess and record complexity issues.

Recommendations

As an interim measure in lieu of an evaluation framework designed specifically for TEC, we recommend a 5-part framework which is built around the following components (see appendices):

1. **NASSS CAT (Project Version),**
2. **NICE ESF (this might require consideration of best fit regarding the most relevant tier)**
3. **budget impact assessment,**
4. **a short practical use case description and**
5. **a simple logic model or set of value propositions.**

The following 14 key requirements are intended as an outline criteria for the development of a consolidated evaluation framework for technology enabled care (CEFTEC). These have been drawn from previous research and limited expert consultation. An evaluation framework should:

1. Include approaches for evaluation of 1) the innovation and 2) its implementation
2. Understand and evaluate the programme theory in terms of a chain of short-term proxy outcomes (e.g. using logic models)
3. Consider the production of practical use cases to aggregate and spread knowledge
4. Consider scalability and sustainability of the intervention
5. Use standardised, common terminology and categories of TEC (potentially to understand outcomes at a categorical level)
6. Be suitable for use by health and care commissioners and people who are not expert in HTA, clinical matters, or digital information technology
7. Enable evaluations to take account of, or incorporate, current evidence and evaluation best-practice for the intervention being investigated
8. Be sufficiently comprehensive to cover the range of TEC most often commissioned in the UK
9. Include defined standards of evidence that must be met for commissioning in the UK health and care system
10. Fit alongside other existing regulation in the UK without duplication or omission of factors
11. Include some means to assess the economic and system-level impacts of TEC
12. Consider being appropriate for technology that has inbuilt development, such as incorporating AI and machine learning
13. Be applicable for proactive and preventative TEC
14. Incorporate consideration of complexity and barriers and facilitators for implementation and output realisation

In terms of the work required, these 14 key criteria will need refinement and extensive consultation to:

- Identify and engage with stakeholders
- Agree systematic terminology and taxonomy
- Select appropriate TMFs

- Develop practical economic and financial evaluation approaches
- Achieve a suitable compromise between academic rigour and universal, practical usefulness
- Consider sources of authority and credibility additional to formal evaluation findings, which might influence decisions
- Produce decision aids and guidance to support use

Document Status

This document is a report of the work carried out to summarise current evidence and develop a universally accessible and comprehensive framework for evaluating technology enabled care (TEC). It sets out the landscape of evaluation theories, models, and frameworks (TMFs), and offers suggestions for how existing approaches might be synthesised, adapted, and utilised. Importantly, the document sets out further areas of investigation and the work required to create a bespoke consolidated evaluation framework for TEC and provides options for how such a framework might be constructed. The document, therefore, explores key issues in the evaluation of TEC by describing 1) the current situation, 2) how current evidence might be applied immediately and 3) work required to develop an evaluation framework that is more appropriate for TEC.

When it comes to adoption and spread of technology enabled care, there are a number of stakeholder groups that have different evidence requirements. This work considers the development of an evaluation framework from the perspective of decision-makers with responsibility for reasonably large-scale implementation. These include developers, service providers, and commissioners. However, an evaluation framework should also be acceptable to researchers and evaluators.

Whilst there is a need for individual people to have access to information to help them decide on the uptake of specific technologies, this is often likely to be a different type of information. For instance, whilst an individual might consider how well a technology integrates with other technologies they use, a commissioner might be interested in the amount of people in a population for whom the technology integrates with other technology. In terms of prioritising benefits, an individual might consider that the most important benefit of a fall-alarm is to provide reassurance for a relative, whereas a commissioner might place greater importance on the potential for speeding up a response and thereby reducing the length of stay in acute care.

Much of the current evidence tends to be in the field of digital health technology (DHT), rather than technology enabled care (TEC). However, interestingly, these two fields are often treated synonymously in the literature. There is also a wealth of relevant information in the generic implementation science literature. In cases where TEC is not the focus, we have considered the transferability of findings.

Document status: Key Points

Aim 1: Review current evidence to describe the evaluation landscape

Aim 2: Develop a specification from current evidence for immediate use to evaluate TEC

Aim 3: Define the work required to create a universally accessible and comprehensive framework for evaluating TEC

- Often likely to be a different information required for different people in different circumstances. An evaluation framework needs to be appropriate and acceptable for a wide range of stakeholders.
- Current evidence mostly focuses on digital health technology (DHT), rather than technology enabled care (TEC).

Background

Following the publication of the Challenge Paper, 'Technology-Enabled Lives: Delivering Outcomes for People and Providers' it is clear that there are significant gaps in the evidence for technology enabled care. Much of the evidence is derived from short-term and small-scale pilot projects, which are often not sustained, thereby limiting the quality of the evidence. The type of evidence can also be problematic, as studies tend to be heterogeneous, providing different types of evidence for different uses and different people.

There are many evaluation frameworks and a very large amount of associated literature available. However, these frameworks tend to be designed around specific purposes, for specific audiences and using different taxonomies or definitions of digital health and care technologies. This makes it difficult to translate knowledge for practical application.

What is lacking, in the sector, is a consolidated approach to evaluation, which enables the aggregation of good quality evidence, is informed by an accessible framework and aimed at supporting key decision-makers to take decisions on uptake, implementation and long-term use of technology to enable care.

In summary, whilst there is some good quality and useful evidence available for some types of technology, there is a large amount of variability. For some technologies the evidence is poor quality, heterogeneous, and lacking in practical utility. There is potential for these evidence gaps to be addressed by the development and application of a 'Consolidated Evaluation Framework for Technology Enabled Care' (CEFTEC).

The following is the result of a rapid piece of work to understand the scale and scope of developing such a framework, by developing a specification for the design of a 'Consolidated Evaluation Framework for Technology Enabled Care'.

Background: Key Points

- Much of the evidence for TEC is derived from heterogeneous, short-term and small-scale pilot projects, which are often not sustained
- We are lacking a consolidated approach to evaluation, which enables the aggregation of good quality evidence, aimed at supporting key decision-makers
- There is potential for evidence gaps to be addressed by the development and application of a 'Consolidated Evaluation Framework for Technology Enabled Care'

Methods

The project was a desk-based investigation conducted over 12-weeks (during September, October, and November 2023), incorporating a limited amount of stakeholder consultation and formed into the following three work-packages (WPs).

WP1: Evidence search

We designed a search strategy to capture existing evaluation theories, models, frameworks and taxonomies. Alongside this formal search, members of the team searched for grey literature and additional influential literature.

WP2: Evidence review

The theories, models, frameworks and taxonomies were critically reviewed to describe their strengths and weaknesses and develop criteria on which to compare them.

The results of the search were filtered (using inclusion/exclusion criteria), prioritised (in terms of importance for contributing to the specification) and summarised. It was noted that two consolidated frameworks are well-known and designed for universal application to evaluate digital health and care technologies (NICE ESF & NASSS framework). As these were closest to the specification requirements and (to an extent) designed for care technologies, they were scrutinised in greater detail.

WP3: Evidence synthesis

The synthesis considered the appropriateness of the available evaluation frameworks, including how these fit alongside the recently developed typology for TEC (Alden, 2024). Input from key stakeholders was sought regarding the range of specific purposes for the consolidated framework. Any gaps or shortcomings in the current frameworks were described, incorporating evidence from the informal evidence search. As economic and financial consequences of the adoption of technology are often critical to promote sustained use, economic approaches were also considered. The evidence was used to indicate how an improved evaluation framework for TEC might be designed, what it might include, how it might be used, and by whom.

Outputs

One of the outputs for the short study is an annotated bibliography of relevant literature. We have also created a live directory of Theories, Models and Frameworks (TMFs). The main output is the specification for a 5-part evaluation framework for immediate use, which has taken into account and incorporated important current knowledge.

Rather than being designed specifically for the evaluation of TEC, this interim solution is a combination of current frameworks and practices. The 5-part framework has not been prioritised for evaluation of TEC and could therefore be reduced in terms of size and complexity and improved in terms of coherence and consistency. Some elements could be challenging for people with little evaluation experience, there is separate guidance and advice for completion of the separate elements and the language used could be confusing or inappropriate (e.g. referring to DHT rather than TEC).

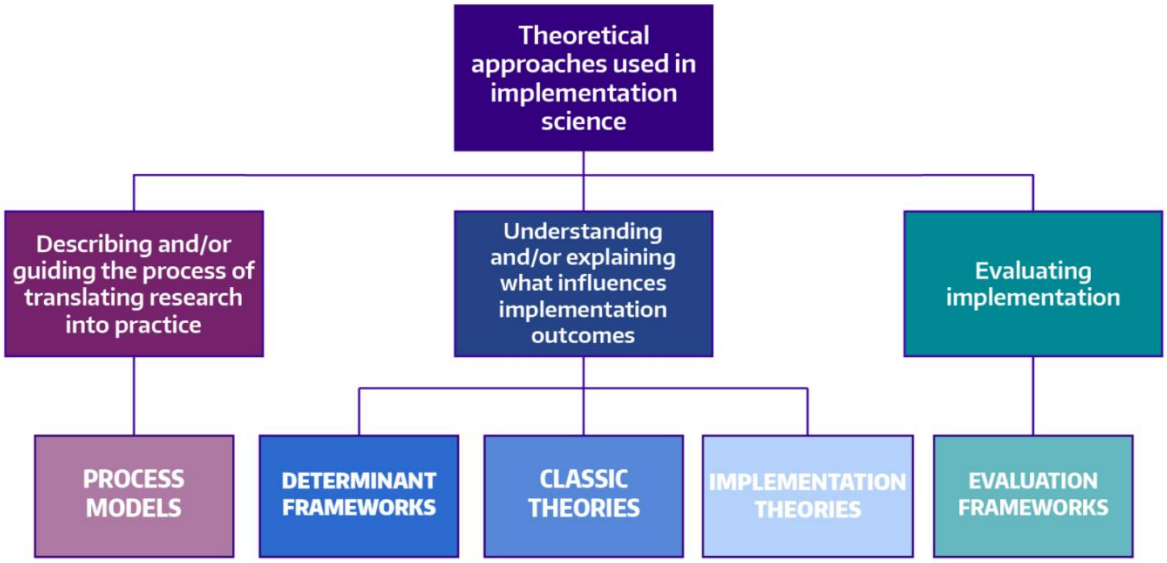
In recognition that this interim solution has specific flaws and difficulties, we have also developed a set of initial criteria and key tasks to develop a ‘Consolidated Evaluation Framework for Technology Enabled Care’ (CEFTEC).

Findings

Current Evaluation Situation

The current evaluation landscape includes a wide range of theories, models, frameworks (TMFs) and approaches. Many of these have foundations in implementation science literature and practice. Indeed, consolidated evaluation frameworks are routinely constructed from TMFs that have been developed for implementation (and evaluation) purposes. The intersection of evaluation literature within the field of implementation science is indicated in the following diagram.

How the implementation science literature intersects with evaluation literature



Adapted from: Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci.*

https://impsciuw.org/implementation-science/research/frameworks/ (Accessed 04.10.23)

Evaluation Theories, Models, and Frameworks (TMFs)

There are some key publications that help to define TMFs, such as the following:

- Tabak et al (2012) Bridging Research and Practice: Models for Dissemination and Implementation Research https://www.sciencedirect.com/science/article/abs/pii/S0749379712003893?via%3Dihub
- Nilsen (2015) Making sense of implementation theories, models and frameworks https://implementationscience.biomedcentral.com/articles/10.1186/s13012-015-0242-0

Individual evaluation TMFs are designed for specific purposes, and they approach evaluation from various perspectives. Therefore, they are not useful for generic use. For example, frameworks could be based around the following.

- Types of technology (e.g. **Information Systems** Design Theory (ISDT), Model for Assessment of **Telemedicine**, Esser & Goossens framework for **teleconsulting** (2009), Mobile App Rating Scale (2015)), or
- Types of users (e.g. Staggers and Parks **Nurse-**Computer Interaction Framework, Mahlke's **User** Experience)

Alternatively, frameworks could be based on the intended use of evaluation outputs. Evaluation outputs could be intended for understanding different aspects of an intervention or informing types of decisions, as shown in the following examples.

- Sustainability (Dynamic **Sustainability** Framework), acceptability (Technology **Acceptance** Model (TAM)), adoption (Clinical **Adoption** Framework),
- Disinvestment (Choosing Wisely **Deimplementation** Framework),
- Economic consequences (Comprehensive **HTA** framework (2002)),
- Organisational and individual **alignment** (Fit between Individuals, Task and Technology (FITT) framework),
- Implementation (Generic **Implementation** Framework, PARiHS, Knowledge to Action (K2A))
- Risk (Lewis **risk** framework (2014)) etc.

Alternatively, evaluation approaches could focus on a specific mid-range theoretical approach (Merton, 1957). such as the following.

- Resource Dependence Theory
- Health Belief Model
- Self Determination Theory
- Social capital theory
- Protection motivation theory

Evaluation frameworks based on these mid-range theories are often focused on psychological theories of human behaviour and require assumptions to be made regarding the relative importance of these perspectives. The prioritisation of single perspectives presents significant limitations for the evaluation of complex interventions. For example, frameworks based on the health-belief model prioritise the following assumptions about human behaviour.

> "in order for behaviour to change, people must feel personally vulnerable to a health threat, view the possible consequences as severe, and see that taking action is likely to either prevent or reduce the risk at an acceptable cost with few barriers. In addition, a person must feel competent (have self-efficacy, eg. Bandura, 1997) to execute and maintain the new behaviour. Some trigger, either internal ... or external ..., is required to ensure actual behaviour ensues".
>
> (Nisbet and Gick ,2008: 297)

The Health-Belief model, therefore, prioritises the view that behaviour change is a rational process, resulting from weighing up risk, costs, and barriers within a context of self-efficacy. The model involves inherent assumptions that education and training, around health risks and how to reduce these risks, results in uniform behaviour change. These assumptions have been criticised for these simplistic assumptions, which clearly do not hold true in all circumstances. There are many other significant influences on health-related behaviour. Whilst these heuristic approaches can be useful to explain how some outcome patterns from interventions might come about, they have severe limitations, and their importance or appropriateness should be judged on a case-by-case basis.

Contemporary theory-led evaluation approaches (e.g. Pawson, 2014) emphasise the complexity of interventions that rely upon or are intended to create behaviour change. Evaluation of TEC interventions should therefore be considered in a framework that is able to incorporate a wide range of potential behavioural theories and outcome patterns to describe what works, for whom, in what circumstances and why.

In terms of universally applicable theories of behavioural change, consolidated or integrative frameworks that incorporate a wide range of potentially important theories (e.g. Abraham and Michie, 2008; Cane et al, 2015) are considered better able to be universally applied and better able to describe the complexity of how specific interventions, or combinations of interventions result in particular outcome patterns.

Therefore, to have widespread application, the development of evaluation frameworks is usually carried out by combining various relevant TMFs. This allows the framework to be useful for the required purposes and people, and to be relevant for the context.

We have gathered TMFs from websites and a literature search to create a living directory, which currently includes 137 TMFs: TMF Living Directory

The key sources for these are the following references that describe framework development projects:

1. Rouleau et al (2023) of 68 frameworks (pre-print)
2. Heinsch et al (2021) of 36 frameworks

3. Greenhalgh et al (2017) of 28 frameworks (NASSS framework)
4. Unsworth et al (2021) of 8 frameworks (NICE's ESF)
5. Dissemination & Implementation Models [Internet]. dissemination-implementation.org. Available from: https://dissemination-implementation.org/

We have collated the TMFs used in each of these framework development projects, which are listed here: Source TMFs for main consolidated frameworks

There are 2 main approaches for frameworks when carrying out an evaluation. The first is to create a bespoke framework from a range of TMFs for each evaluation. The second approach is to use a consolidated framework, which has been constructed from various TMFs and can (in theory) be applied generically to any evaluation.

Bespoke Frameworks

Owing to the need for flexibility, contextual relevance, and different stakeholder requirements, evaluation frameworks are often constructed for each individual evaluation by choosing the best approach for a range of different activities.

This is the approach promoted by websites such as 'Better Evaluation'. **The 'Better Evaluation Rainbow Framework'** (Better Evaluation, 2023) organises methods and processes in terms of the range of tasks required for an evaluation. These tasks include 'Managing an evaluation', 'Describing activities, outcomes, impacts and contexts' and 'Reporting and supporting use of findings'. These tasks are broken down into smaller tasks and approaches which are informed by practical needs, TMFs and approaches. This is more of a list of key principles and elements to consider when evaluating any intervention (similar to the University of Sheffield's 'Real-World Evaluation' short course (Ariss & Nasr, 2024)), rather than a way of standardising evaluations.

A similar approach is taken for the **online 'Dissemination and Implementation Webtool'** (Dissemination and Implementation Models in Health, 2023). The initial set of TMFs for this website were selected from two reviews of the dissemination and implementation literature (Tabak et al, 2012; Mitchell et al, 2010). TMFs are added through expert recommendations and reviews of models as they become available (e.g., Wilson et al., 2010; Birken et al., 2017; Strifler et al., 2018).

The website has a large range of filters, including 'Constructs' such as Adoption, Costs, Goals, Health Equity, Process, Reach, Translation etc. and Socio-ecological levels from 'Policy', 'System' and 'Community' to 'Organization' and 'Individual'. The website contains 114 different models and will suggest appropriate models, based on the filters used. For example, filtering for 'Implementation', 'Individual' and 'Awareness' returns four models (Active Implementation Framework; Choosing Wisely Deimplementation Framework; Exploration, Preparation, Implementation, Sustainment (EPIS) model; and the Theoretical Domains Framework). Each of these has different fields of origin and were designed for specific purposes. The website includes tools and guidance for selecting and combining appropriate TMFs. Therefore, for each evaluation, the website is used to create a unique and bespoke framework from an immense range of possible permutations.

The '**Theory, Model, and Framework Comparison and Selection Tool (T-CaST)**' (Birken et al., 2018) takes a similar approach (https://impsci.tracs.unc.edu/tcast/#gf_4). It is a related product from the Dissemination and Implementation Methods Unit at the University of North Carolina. The tool is linked to the TMFs inventory maintained by the 'Dissemination and Implementation Webtool' and is primarily a decision-making tool for selecting appropriate combinations of TMFs.

Consolidated Frameworks

A different approach to framework construction is taken for frameworks that are intended to be used generically, for any evaluation. These include the following commonly known frameworks:

NASSS Framework (Greenhalgh et al, 2017): A framework for theorizing and evaluating non-adoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies; to predict and evaluate the success of a technology-supported health or social care program. This framework used 28 TMFs. NASSS Framework

NICE Evidence Standards Framework (Unsworth et al, 2021)**:** A framework to guide developers and commissioners on the levels of evidence needed for the clinical and economic evaluation of Digital Health Technologies by health and care systems. This framework used 8 TMFs. NICE_ESF for Digital Health Technology

We have summarised and assessed the strengths and weaknesses of these frameworks in a separate document: Strengths and weaknesses of main consolidated frameworks.

However, a recent attempt to create a consolidated framework for digital health interventions (Rouleau et al, 2023) exposed weaknesses in the approaches taken by existing consolidated frameworks and exposed a divide between academia and practice. The project applied a comprehensive search strategy to identify relevant TMFs and used 68 TMFs from 156 sources. Some of the key messages from this project are summarised below.

Key messages from Rouleau et al, 2023.

These researchers set out to develop a standardised reporting structure inclusive of a digital health intervention's function, setting, target user(s), and intended outcomes. However, they found that current evidence-based approaches were not familiar to stakeholders outside of academia.

> *"The knowledge users reflected that most of the prevailing TMFs identified in this scoping review were not familiar to them, highlighting a gap between academic literature and practice.* ***They were more familiar with Benefits Evaluation Framework and the Quadruple Aim."***

Whilst there is currently no evidence regarding the similarity of the situation between digital health technology and technology enabled care, we have no evidence to suggest that there are significant differences. Therefore, it could be assumed that a similar divide exists between academic evaluators and commissioners or practitioners that carry out evaluation as part of their implementation role. However, it should also be recognised that this study was conducted in Canada, and it is not proven that the same situation prevails in the UK. If the situation has similarities, it is likely that commissioners in the UK will be familiar with different frameworks, models, or theories.

Sixty-eight distinct TMFs were identified across 85 individual studies. The six prevailing TMFs are: 1) Consolidated Framework for Implementation Research (CFIR), 2) the Reach, Effectiveness, Adoption, Implementation, and Maintenance Framework (RE-AIM), 3) the Technology Acceptance Model (TAM), 4) the Unified Theory on Acceptance and Use of Technology, 5) the Diffusion of Innovation Theory, and 6) Normalization Process Theory. The most common intended roles of the six TMFs was to inform data collection (n= 86), to inform data analysis (n=69), and to identify key constructs that may serve as barriers and facilitators (n=52).

The authors draw the following conclusions:

> "As TMFs are most often applied to support data collection and analysis, researchers should consider more clearly synthesizing key insights as practical use cases to both increase relevance and digestibility of their findings. What was once an opportunity to develop a standardized reporting structure inclusive of digital health interventions function, setting, target user(s), and intended outcomes is quickly becoming an imperative in order to ensure ongoing technology transformation efforts are evidence-informed rather than anecdotally driven."
>
> (Rouleau et al, 2023)

The question regarding familiarity of different TEC evaluation frameworks with academic audiences compared to other UK stakeholder groups, such as service-users, local authority, NHS or ICB commissioners requires further consideration. It is not currently known whether this gap is significant, or which TMFs are preferred by commissioners or providers of TEC. Without this information, it is not possible to know whether there are widely used TMFs, or to assess their suitability for wider use or adaptation.

Current Evidence: Key Points

- Evaluation landscape includes around 137 different theories, models, frameworks (TMFs) and approaches. Many with foundations in implementation science

- Individual evaluation TMFs are for specific purposes and adopt various perspectives. They are not useful for generic use
- Need to incorporate a wide range of behavioural theories and outcome patterns to describe what works, for whom, in what circumstances and why
- Therefore, to have widespread application, evaluation frameworks usually combine various relevant TMFs (bespoke for each evaluation or using consolidated frameworks)
- There seems to be a divide between approaches used by academics/evaluators and other practitioners
- Consider more clearly synthesizing key insights as practical use cases (see appendix)

The NICE Evidence Standards Framework for Digital Health Technology

In terms of currently available evaluation frameworks, despite having some specific weaknesses, the NICE ESF seems a good fit. It has substantial alignment with the requirements for this project as it is designed to be a:

- universally applicable,
- realistically achievable,
- consolidated evaluation framework,
- which is usable by non-expert evaluators.

It is intended for technology companies to understand the kinds of evidence needed to facilitate commissioning or purchasing decisions in the NHS and care system. It is also intended to be used by evaluators and innovators and to support purchasing and commissioning decisions. However, there are several aspects where it is not fit for purpose as a TEC evaluation framework. These are described below.

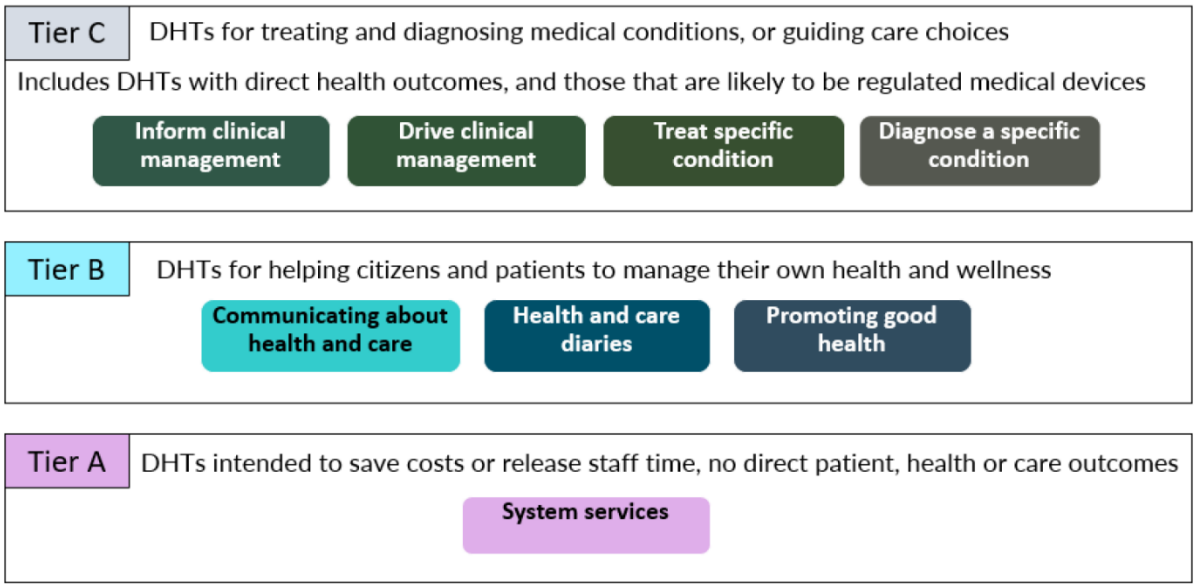
Equivalence of DHTs and TEC in the NICE ESF

We are recommending (interim) adoption of the NICE ESF, a particular problem is how to map TECs into the 3 DHT tiers. Currently this will take some thought and judgement by the evaluator. If this were to be adapted for a more appropriate evaluation framework, this issue will probably require a good deal of consultation to reach agreement with all stakeholders. The DHT 3-tiers are summarised below.

Tier A: System service. DHTs intended to release costs or staff time, or to improve efficiency.

Tier B: Communicating about health and care & Health and care diaries & Promoting good health

Tier C: Inform clinical management & Drive clinical management & Diagnose a condition & Treat a condition



(NICE, 2022)

Weaknesses of the NICE ESF

What the ESF is weak on is implementation, context, theory, adoption and spread. For instance, scalability is only considered in terms of technical ability to manage greater numbers of uses (e.g. server capacity). There is an assumption that if it is credible to health/care staff (standard 8, from the ESF) and has had some sort of pilot (standard 15) then it will be scalable and widely adopted. We know that this is not the case.

So, it is a minimum addition to include consideration of adoption and spread and evaluation of the implementation in context. There is a single element of standard 12, which considers implementation and context ('any influential contextual issues that may act as barriers for enablers to implementation'). However, this is such an important consideration for complex interventions that it should be afforded greater prominence. For instance, additions could include elements of the NASSS framework and a means of capturing implementation issues and context dependencies. This latter issue could be resolved through the inclusion of an implementation science framework such as the CFIR or short practical use case descriptions (as described in Rouleau et al, 2023).

The NICE ESF is also weak regarding understanding the theory of how and why an intervention is expected to result in specific outcomes. This is largely confined to expectations in terms of technical changes to pathways and numbers of people expected to experience benefits. Without a consideration of the key mechanisms operating between the intervention and outcomes, it will be difficult to interpret findings, specifically when comparing evaluations of similar technology implementations with contrasting findings.

Stakeholder feedback on the NICE ESF

Following our assessment of the available TMFs, we concluded that the NICE ESF framework could hold promise as a template for the development of a consolidated framework for TEC. As part of our work, an early discussion document was circulated to a small number of stakeholders for feedback. This included the criteria that were used for the development of the NICE evaluation framework**.** The aim of this exercise was to review the use of the NICE framework as a template for the development of a consolidated framework for TEC. The table below summarises the feedback gained.

	Requirement	Opinion	Notes/Adaptation
1.	be suitable for use by health and care commissioners and people who are not expert in HTA, clinical matters or digital information technology	Include (essential)	Needs to be easily understood by commissioners in every type of setting. Adapted from health and clinical outcomes, to social care and prevention.
2.	be sufficiently comprehensive to cover the range of DHTs that are most often commissioned in the UK health and care system	Adapt (exclude medical devices)	Proactive and preventative TEC is not well understood Possibly the lack of an evidence base limits commissioning
3.	take account of the current evidence levels available for digital tools across the spectrum of DHT functions	Discard/ Adapt	Current evidence levels are incomplete and inconsistently measured. Comparing new proactive and preventative technologies to existing health tech may not be possible or desirable. Do we need to be tied to prior work that hasn't succeeded?
4.	include defined standards of evidence that must be met for commissioning in the UK health and care system	Include/ Adapt	Should set out the standards of evidence required in order to meet the needs of health and social care (and housing)
5.	fit alongside other existing regulation in the UK without duplication or omission of factors	Adapt	Yes, where regulation is known and applicable, but with recognition that some current standards are not fit for purpose with regard to modern software development or platforms. DTAC and MHRA standards are difficult to meet for connected care platforms that continue to develop.
6.	include some means to assess the economic and system-level impacts of DHTs.'	Include	Absolutely essential and one of the primary goals of the study.

7.	Allow multiple evaluation programmes to be described in terms of common criteria and aggregated as they contribute to an incremental build-up of evidence	Include	Absolutely essential because we do not have the time to wait for one big study to deliver answers in 2025. We need to create a set of standard success measures that should be applicable to any TEC project or at least any proactive & preventative TEC project

In summary, considering the development of the NICE framework, these early recommendations indicate that an evaluation framework should:

1. Be usable and understandable by non-experts in evaluation in all settings
2. Be comprehensive to cover a wide range of TEC, with clear exclusion/inclusion criteria
3. Consider whether/how to include current evidence levels for some types of TEC (possibly using common terminology)
4. Set out the standards of evidence required (however, for the NICE framework this is based on levels of risk for end-users, which might not be appropriate)
5. Fit along existing regulation, when fit for purpose (the NICE framework aligns with DTAC and MHRA)
6. Include means to assess economic and system-level impacts
7. Allow description using common terminology and criteria to allow aggregation of findings across numerous small studies
8. Be applicable for proactive and preventative TEC

NICE Evidence Standards Framework: Key Points

- The NICE Evidence Standards Framework (ESF) for DHT could be a promising starting point for designing a more appropriate framework for TEC
- Currently, the evaluator's judgement is needed to map TEC onto 3 DHT tiers of the NICE ESF
- The NICE ESF is weak on:
  - Implementation
  - Context
  - Theory
  - Adoption
  - Spread

The NASSS framework

A commonly used framework for evaluating digital health and care technologies is the **non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework** (Greenhalgh et al, 2020). The framework was developed as a response to the understanding that many organisational implementations of digital health technologies fail. A key reason for this failure is considered to be the rational, linear approach to implementation (embedded in traditional management approaches such as PRINCE-2; TSO 2009), which is not suited to the complexity of implementing digital innovations.

The NASSS framework therefore encourages the consideration of complexity to identify barriers to adoption, sustainability and spread. Interestingly, the authors note that these barriers cannot always be addressed. In testing the framework (including care technologies such as GPS trackers and pendant alarms), the authors concluded that complexity in multiple domains either prevents mainstreaming or results in intended outputs not being achieved (Greenhalgh et al, 2018).

The framework has the following seven domains of investigation that can each be categorized as simple, complicated, or complex:

1. The illness or condition
2. The technology
3. The value proposition
    a. Supply side value (to developer)
    b. Demand side value (to patient)
4. The intended adopters
    a. Staff
    b. Patient
    c. Carers
5. The organisation(s) implementing the technology
6. The external context (wider system) for innovation
7. Embedding and adaptation over time

Regarding the purposes of selecting or developing a consolidated framework to produce comparable data, the focus of the NASSS framework on complexity would seem to preclude it from consideration, as the approach focuses on the individuality of implementation and takes the unique contextual factors into consideration. Indeed, the authors acknowledge that the consideration of complexity results in 'messy' data.

> "A limitation of the NASSS-CAT tools, according to those who favor a more rationalistic approach, is that they are relatively unstructured and likely to generate messy data. However, the strength of these tools, we believe, is that for the very reason that they are unstructured, they are particularly suited to addressing the hypercomplexity of many health and care technology projects." (Greenhalgh et al, 2020, p.8)

However, the understanding that many digital health and care implementation projects fail, and the lack of data about why and how they fail should not be dismissed. Therefore, it would be prudent for developers, providers, and commissioners to consider evidence related to complexity when designing, implementing, and evaluating care technology.

A new pre-print scoping review of published applications of the NASSS framework (Shin et al, Nov, 23rd, 2023), includes 57 studies (53 digital applications) and looks at the application of the NASSS framework over time (5 years since its inception) in research.

The authors also concluded that 'implementation is a highly complex process that requires careful preparation to ensure implementation success' (Shin et al, 2023, p.3):

> *"Most studies used the NASSS retrospectively, which may be attributed to the framework's novelty. However, this finding highlights the need for prospective and concurrent application of the NASSS within the implementation process. In addition, almost all included studies reported multiple domains as barriers and enablers to implementation, indicating that implementation is a highly complex process that requires careful preparation to ensure implementation success." (Ibid)*

In terms of who is using the tool (real-world usage), the IRIHS team should be able to report on this, because users have to complete a form before they are allowed to download the NASSS-CAT tool. However, the following demonstrates the range of applications considered.

> *"Of the 53 digital applications, approximately half of them were telemedicine/virtual care (n=24), followed by personal health devices (n=10), knowledge generation applications (n=9), and digital interventions (n=10), such as internet-based Cognitive Behavioural Therapy (iCBT)."* (Shin et al, 2023, p.8)

The framework was used prospectively (to inform design) and concurrently, alongside implementation. However, most studies (59%) used the framework retrospectively (to evaluate implementation).

> *"In terms of timing, most studies conducted their analyses using the NASSS framework retrospective to implementation, for example to analyze why implementation did or did not succeed in terms of adoption, non-abandonment, scale, spread, and sustainability of the innovation in a given context (n=33). The rest applied the framework prospectively to inform future implementations (n=15), or concurrently with implementation (n=8). Approximately one third (32%) of included studies reported implementation barriers and enablers related to all 7 NASSS domains, and 21% reported barriers and enablers related to 6 domains."* (Shin et al, 2023, p.18)

Similarly to other TMFs, it is not clear to what extent the framework is used by academic researchers and evaluators or by developers, providers and commissioners. However, this information could potentially be gained from the IRIHS team at the University of Oxford.

Other studies, such as the MALT project (Mainstreaming Assisted Living Technologies) have also identified barriers and facilitators for implementation of care technology (Taylor et al, 2014), which would require consideration in the case of development of a consolidated TEC evaluation framework.

NASSS Framework: Key Points

- NASSS framework encourages consideration of complexity to identify barriers to adoption, sustainability and spread
- Owing to complexity, many digital health and care implementation projects fail. The NASSS can help provide data about why and how they fail
- It is not clear to what extent the framework is used by academic researchers and evaluators or by developers, providers and commissioners
- There are four different tools available to assess and record complexity issues:

  Short checklist, Long checklist, Project Version checklist, Interview schedule

Next steps

The current short, medium, and long-term recommendations are outlined below. Approximate timescales are given. These are dependent on funding and practicalities around capacity and capability. However, we anticipate that much of this work can be carried out in parallel, rather than sequentially.

Short-term:

a. **Immediate approach**: Recommend an immediate approach for TEC evaluation, which as far as possible draws upon current evidence, is universally applicable, has potential for aggregation and comparison of findings, and can be used by practitioners with limited evaluation knowledge or resources.
b. **Compromise:** Recognise that any evaluation framework will not be the best for every technology in every setting or provide the best and most appropriate evidence for all stakeholder decisions. However, it is necessary to make an informed compromise between evidence-informed academic rigour and practicality and usefulness.

Medium-term:

c. **Taxonomy (4-months)**: Adapt and adopt a common language to describe typologies of TEC that are appropriate for comparing and combining evaluation findings.
d. **Specification for development (6-months)**: Create an agreed specification for the development of a consolidated evaluation framework for TEC, that service & technology providers and commissioners can adopt at the earliest opportunity, to ensure that project evaluations have optimum usefulness, and with a greater likelihood that commissioners and users will take up their solutions and recommendations.
e. **Build evaluation framework (18-months)**: Use this agreed specification for building a consolidated framework for evaluation, where multiple evaluation programmes and projects can be described in terms of common criteria and evidence incrementally aggregated, to support the growth of the sector.
f. **Evaluation environment (12-months)**: All of this may sit alongside physical and virtual environments for trial and evaluation of TEC solutions, such as living labs that are currently under development.

Long-term possibilities:

g. **Repository**: Consider longer-term development towards some form of semi-automated environment, where evaluation data is captured, processed and made available to users, commissioners, and researchers.

The first objective should therefore align with point ‘a’ above, to develop an immediately usable and agreed specification for evaluation of TEC from existing evidence and drawing on existing TMFs and practices. This can then be combined with the development of common language and typologies of TEC (Alden, 2024). The second (medium-term) objective is to agree an optimum specification and translate this into the development of a consolidated evaluation framework for TEC (CEFTEC).

The specification for an immediately usable 5-part evaluation framework for TEC is described below and all of the necessary elements are included in the appendices. We have also described the medium-term work required to produce a consolidated framework, which will have improved integration and cohesion and be designed specifically for evaluation of TEC innovations.

The 5-part framework is designed to provide comprehensive evaluation evidence, which will be compatible with evaluations using the proposed consolidated framework. It is anticipated that the core information and approaches will be similar, although for the consolidated framework, ease of use and appropriateness will be improved, and elements will be subject to prioritisation and streamlining. Therefore, effort will not be wasted in the short-term as evaluation findings will be able to be combined and compared with ease.

Short-term recommendation: Use of a 5-part evaluation framework

As an interim measure in lieu of an evaluation framework designed specifically for TEC, we recommend a 5-part framework which is built around the following components:

1. **Adoption and Spread:** Completion of the NASSS CAT framework complexity tools to identify areas of complexity that will be a barrier to adoption and spread. The 'project assessment over time' tool will be most suitable for evaluations as it provides a view of implementation at a point in time. For ease of reporting, it provides a complexity score for each section. It also has the benefit of forecasting whether the project is likely to become more or less complex.

2. **Technology Evaluation:** Adoption of the NICE evidence standards for digital health technology (NICE, 2022): these might need some minor adaptation or use of judgement by users in the short-term (e.g. appropriateness of language). The levels of risk might lack appropriateness and consultation would be beneficial to decide whether they can stay for now or require rapid adaptation. In the longer-term, the framework needs scope to include in-built risk monitoring, and the language needs changing to focus on care rather than health technology.

3. **Economic Evaluation:** For now, we would recommend the economic evaluation approaches in the NICE ESF (specifically budget impact analysis (BIA)). Organisational financial considerations are usually considered most relevant for successful implementation and sustainability; therefore a Budget Impact Analysis should be considered a minimum standard.

4. **Implementation Evaluation:** Context will need to be captured. A useful approach would be to develop a specification for short practical use case descriptions (as described in Rouleau et al, 2023). We have analysed the key components of short practical use case descriptions and produced a table to systematically capture important information (see appendices).

5. **Logic Model:** It is important to explicate the innovation theory (assumptions underlying the innovation). This theory will include value propositions and why certain outcomes are expected for certain people in certain circumstances. In its simplest form the theory provides causal links between activities and outputs. Once developed, the theory could be incorporated into practical use cases (above). A simple logic model template is included in the appendices.

Immediate 5-part Framework:

Key Points

In summary, a useful minimum interim approach would include the:

1. NASSS CAT (Project Version: for monitoring complexity over time),
2. the NICE ESF (with individual judgement used to decide on tiering)
3. budget impact assessment (BIA),
4. a short practical use case description and
5. a simple logic model.

This will provide comprehensive evidence that can be integrated, compared, and combined with findings produced using a consolidated evaluation framework specifically for TEC that we propose developing. Ensuring that short-term effort is not wasted in the event of planned developments.

Medium-Term recommendation: Create an agreed specification for the development of a consolidated evaluation framework

Adaptation of the NICE ESF criteria

Regarding a useful starting point for agreeing a framework for development of a consolidated evaluation framework for TEC, there is potential for the adaptation of NICE ESF criteria. The NICE ESF for digital health technology has a transparent set of criteria that were used to develop the framework (Unsworth et al, 2021). These 6 criteria could be usefully considered and adapted as they are similar to the requirements for the TEC AA:

> NHS England set the following requirements that the ESF should:
>
> 1. be suitable for use by health and care commissioners and people who are not expert in HTA, clinical matters or digital information technology,
> 2. be sufficiently comprehensive to cover the range of DHTs that are most often commissioned in the UK health and care system,
> 3. take account of the current evidence levels available for digital tools across the spectrum of DHT functions,
> 4. include defined standards of evidence that must be met for commissioning in the UK health and care system,
> 5. fit alongside other existing regulation in the UK without duplication or omission of factors,
> 6. include some means to assess the economic and system-level impacts of DHTs.'

The NICE framework is for digital health technologies (DHTs). Whilst it is intended for deployment within health and social care, much of the terminology in the ESF concerns health technologies. Importantly, the specific standards that should be used for an evaluation depend on categorisation of the DHT into one of the 3-DHT tiers. So, a big question is 'what is the equivalence (and what are the differences) between DHTs and TECs?' There is clearly an overlap, but there are also big differences. Where there are overlaps (i.e. when a TEC is also a DHT), then there are strong arguments that it should be subject to the NICE ESF. This is one area where the taxonomy of TEC (Alden, 2024) could be useful in helping to decide which framework takes precedence.

There are several areas where the specifications for the NICE ESF requires further consideration regarding the TEC framework requirements. Importantly, the framework excludes consideration of safety issues:

> "The ESF was not intended to cover safety issues nor to be a regulatory tool: in the UK, the regulation of DHTs that are categorised as medical devices is governed by the Medicines and Healthcare products Regulatory Agency (MHRA)."

The role of regulatory frameworks, such as MHRA regulations need careful consideration. The extent to which specific regulatory frameworks are (or are not) applicable to TEC interventions can sometimes be decided with clarity. However, in other circumstances the judgement might not be straightforward. It should be noted, for instance, that current MHRA regulations are designed for medical devices and may not be fit for purpose or appropriate when considering some software products or platforms or purely care technologies.

Whilst the safety of an intervention should be a commissioning concern, it is not sure how, or whether, this should be included in an evaluation framework or treated as a separate issue. The NICE ESF, despite being organised around levels of risk, treats regulatory issues around intervention safety as a separate issue. Given that TEC could encompass telehealth, virtual wards etc. it should be considered that medical devices could be included in a combined TEC intervention. Especially where medical devices are used in conjunction with TEC as part of a package of care, there should be means to acknowledge or incorporate medical devices into a TEC evaluation framework.

In several key areas, the NICE ESF defers to MHRA guidance and regulations. For instance, since 2022 the NICE ESF has included consideration of artificial intelligence and synthetic data. For DHTs that incorporate machine learning, it is recommended to follow the MHRA guiding principles on good machine learning practice for medical device development. It is not clear how well this guidance aligns with TEC.

Criteria for development of a consolidated evaluation framework for TEC

The following is intended as initial criteria to frame the specification and design of a consolidated evaluation framework for technology enabled care (CEFTEC). The following 14 criteria have been drawn from previous research and limited expert consultation.

1. Include approaches for evaluation of 1) the innovation and 2) its implementation
2. Understand and evaluate the programme theory in terms of a chain of short-term proxy outcomes (e.g. using logic models)
3. Consider the production of practical use cases to aggregate and spread knowledge
4. Consider scalability and sustainability of the intervention
5. Use standardised, common terminology and categories of TEC (potentially to understand outcomes at a categorical level)
6. Be suitable for use by health and care commissioners and people who are not expert in HTA, clinical matters, or digital information technology
7. Enable evaluations to take account of, or incorporate, current evidence and evaluation best-practice for the intervention being investigated
8. Be sufficiently comprehensive to cover the range of TEC most often commissioned in the UK
9. Include defined standards of evidence that must be met for commissioning in the UK health and care system
10. Fit alongside other existing regulation in the UK without duplication or omission of factors
11. Include some means to assess the economic and system-level impacts of TEC
12. Consider being appropriate for technology that has inbuilt development, such as incorporating AI and machine learning
13. Be applicable for proactive and preventative TEC
14. Incorporate consideration of complexity and barriers and facilitators for implementation and output realisation

Medium-Term Recommendation: Build an evaluation framework for TEC

A comprehensive review has not identified any consolidated evaluation frameworks that are currently fit for purpose on their own. Therefore, there is a strong case to be made for work to be carried out to design a consolidated evaluation framework for technology enabled care. Following refinement and general agreement of the initial required criteria above, the following sets out the key considerations and tasks for constructing such a framework.

Consider incorporating existing TMFs

The development should consider how relevant, evidence-based theories, models and frameworks (TMFs) have been searched for and incorporated into other consolidated frameworks. It should consider and prioritise the relative importance of existing TMFs. It is important that where there is a relevant, evidence-based TMF its incorporation into or adaptation for the evaluation framework is considered. The process should use learning from the development of other consolidated frameworks. Therefore, the living directory of TMFs should be constantly reflected upon. However, development should be firmly based on co-production with key stakeholder groups. The NICE ESF is a useful example of this type of approach.

Use systematic terminology and taxonomy

During development the primary consideration should be suitability for use by non-experts in evaluation or digital technology. The work commissioned by the TEC Action Alliance, to develop a systematic terminology and taxonomy of TEC should be integrated to aid aggregation of evidence and ensure comprehensive coverage of the range of TEC. The usefulness of systematic case examples should be explored. This work should also consider the overlap between, and concurrent use or integration of TEC and DHTs.

Incorporate complexity concepts and programme theory

Complexity concepts and descriptions of settings should be incorporated, especially to inform the likelihood of successful implementation in other contexts. In this regard, it will be important to include implementation evaluation (process) alongside innovation evaluation (summative). Include elements of programme theory so that chains of short-term proxy outcomes can be measured, as measuring definitive long-term outcomes can be difficult, time-consuming and expensive.

Develop practical economic and financial evaluation

The development of economic and financial evaluation elements of the consolidated framework should also concentrate on creating a common set of terminology. The evaluation approaches should be based on real-world pragmatic constraints and include various levels and types of evidence. For example, whilst some evaluations might be focused on the financial impact to a service or organisation, others might have a strong concern with social return on investment, social value or system-wide economic benefits across a range of organisations. Initially, these approaches could be based on the HM Treasury Green Book and Magenta Book and the economic evaluation approaches suggested in the NICE ESF. However, these should be strongly informed by usefulness for decision-makers.

Engage stakeholders to reconcile the divide between academia and practice

The review has demonstrated that there is likely to be a large divide between evaluations carried out by researchers/evaluators and other practitioners and knowledge users. This has resulted in a dichotomy of either:

1) resource intensive, slow and expensive, academically rigorous and evidence-based evaluation approaches or
2) more practically focused evaluations, which are not based on current evidence or best-practice and have little usefulness beyond the immediate setting.

An evaluation framework development should focus on reconciling these alternative perspectives and, through intensive stakeholder engagement, design academically rigorous and practically useful approaches. This will require the acceptance of compromise between academic rigour and practical usefulness.

A comprehensive stakeholder mapping and engagement exercise would be required to ensure all appropriate views are represented. Stakeholders groups would probably include commissioners, service-providers, innovation developers, researchers, evaluators and service-users.

Consider additional information

Whilst formal evaluation evidence is important for decision-makers, it is also important to consider other sources of authority and credibility that might be influential.

Produce decision aids and guidance to support use

For example, explore the potential use of flow diagrams to include or exclude various elements to add flexibility and appropriateness.

How to develop an improved evaluation framework for TEC: Key Points

We have outlined 14 key requirements as initial guidance to frame the specification of a consolidated evaluation framework for technology enabled care (CEFTEC).

These will require refinement and extensive stakeholder consultation to:

- Select appropriate TMFs
- Agree systematic terminology and taxonomy
- Incorporate complexity concepts and programme theory
- Develop practical economic and financial evaluation approaches
- Achieve a suitable compromise between academic rigour and universal, practical usefulness
- Consider additional sources of authority and credibility that might influence decisions
- Produce decision aids and guidance to support use

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Appendix 1: Additional sources of information

There are various potential sources of information about TEC products, which might have some relevance for TEC providers and commissioners. For example, the Health Innovation Networks (HINs, formerly AHSNs), have responsibility for supporting the adoption and spread of health and social care innovations and some (e.g. Yorkshire and Humber) have dedicated programmes for digital technology. There are also private companies and the NHS to consider. Some examples of these types of resources are described below.

Health Innovation Y&H

https://www.healthinnovationexchange.org.uk/innovations

The Health Innovation, Y&H Innovation Exchange has web pages with information about digital care technologies. Technologies are divided into categories and level of confidence related to whether the innovation is 'in development', 'proven', or 'under evaluation for adoption potential'. The categories of technologies are as follows:

1. System digitisation
2. Support for primary care
3. Improving system flow
4. Independence and prevention
5. Operational excellence
6. Patient activation and self-care
7. Patient safety and quality improvement
8. Workforce resource optimisation

ORCHA

https://orchahealth.com/

The organisation for the review of care and health apps is a private company that provides services and tools, such as an app library and digital health formularies. They are concerned with addressing the barriers to adoption, including awareness, trust, access and governance. They assess health apps and digital health products to ensure they meet relevant clinical, data, privacy, accessibility and usability standards.

https://orchahealth.com/our-products/health-app-library/

The organisation is lobbying for the introduction of an accreditation scheme for third-party healthcare apps verified by the NHS.

https://orchahealth.com/we-hope-the-government-reconsiders-its-decision/ [27 September 2023]

The following describes the main features of a case where they worked with Humber and North Yorkshire Health and Care Partnership to recommend appropriate apps to people on elective care waiting lists.

- Reviewing the most common health conditions, and with a clinical team mapping the most effective apps to each area, based on reviewing data from the hundreds of health app assessments conducted by ORCHA in each field.
- A campaign landing page featuring 10 apps that support the most common health needs faced by those on the elective care waiting list. These include pain management, sleep, general health and fitness, drinking, smoking and mental health and wellbeing.
- Targeted communications to reach those waiting, to drive them to the landing page. This included social media posts, GP practice text messaging, mentions in outpatient letters, and QR code sheets for practitioners.

- Training to a range of clinicians to enable them to feel comfortable recommending apps from the campaign and also to understand how the ORCHA platform can support more widely with their patients.

'During August and September, the programme saw 7,648 people visit the page, and approximately 27% of these people download a health app as a result (1,021 on page downloads and an equal number of off-site downloads).'

https://orchahealth.com/campaign-landing-page-helps-people-on-elective-care-waiting-list/

NHS Apps Library

NHS Apps Library has now been closed and instead they have chosen to link to recommended apps throughout the NHS website.

The apps that they recommend will be selected by clinical policy teams within NHS England and NHS Improvement.

This means that they should:

- meet the required technical and clinical safety standards
- be approved by experts in a particular area, such as mental health policy

SOCRATES

The SOcial Care Rapid evAluation Team (London School of Economics and Political Science, the University of Central Lancashire and King's College London) has limited funding to evaluate a small number of innovations in social care. However, there is no ambition to systematise evaluation, indeed they state that each "rapid evaluation will look different. This is because we will use the most suitable methods to answer the research questions."

https://fundingawards.nihr.ac.uk/award/NIHR153673

It is therefore unlikely that their outputs will be of direct relevance to this work. However, it could be worthwhile to monitor their projects for any evaluations of technology enabled care.

Appendix 2: Additional outputs

- Strengths and weaknesses of main consolidated frameworks
- Source TMFs for main consolidated frameworks
- TMF Living Directory

These documents are available on request. All legitimate requests to supply these documents will be considered. Requests should be directed to the lead author: s.ariss@sheffield.ac.uk

Appendix 3: Literature Search Strategy for TEC Frameworks and Taxonomies

Definition of technology enabled care

Technology enabled care services refers to the use of telehealth, telecare, telemedicine, telecoaching and self-care.

Source: NHS website https://www.england.nhs.uk/tecs/

Search approach

- Electronic database sources: Search in the most common databases searched for TEC i.e. PubMed, Embase, Web of Science.
- Title field search: TEC and framework or taxonomy
- Abstract field search: Occurrence of “framework” or “taxonomy” in the abstract 2 or more times.
- Limits: English language and UK geography filter
- Date limit: Current and in the last 5 years

- Supplementary citation searches of key frameworks e.g. Greenhalgh et al., 2016 with targeted searches within citations for “evaluation”, “evaluate” and “evaluating”.

Criteria

- Process documents of frameworks on TEC i.e. include actionable framework e.g. knowledge translation or evidence-based policy
- Topic: Telemedicine in general including telemedicine speciality
- Setting: In one or multiple settings e.g. primary/secondary/tertiary care, home, hospital, outpatient
- Frameworks or taxonomies post-2016
- Describing development of frameworks
- Use and application of frameworks
- Reviews of frameworks
- International frameworks that apply to UK

Exclusion

- Frameworks not related to patient care e.g. legal frameworks, privacy frameworks, regulatory frameworks, for economic evaluation and value assessment of DHIs, frameworks in clinical trials, competence frameworks.
- Ongoing/unpublished frameworks (e.g. protocols)
- Non-UK and non-English frameworks

Draft MEDLINE search strategy

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 1946 to September 01, 2023
5th September 2023
91 records

#	Searches	Results
1	("digital* health" or "health technolog" or telecare or teleconsultation* or telehealth or tele-health or telemedicine or tele-medicine or ehealth or e-health or "computer based technolog*" or "mobile health" or "mobile medicine" or "mobile technology" or "remote consultation" or "remote health" or "remote medicine" or "remote monitoring" or "remote rehabilitation*" or "technology enabled care" or "virtual health" or "virtual medicine" or "virtual rehabilitation*" or "online consultation*" or mhealth or m-health or telecoaching or teledentistry or telemonitoring or telepathology or teleradiology or telerehabilitation* or tele-rehabilitation*).ti.	32877
2	(framework* or taxonom* or classif* or defin* or standards).ti.	291109
3	1 and 2	514
4	(framework* or taxonom*).ab. /freq=2	98492
5	1 and 4	563
6	3 or 5	870
7	limit 6 to (english language and yr="2018 -Current")	550

8	exp Great Britain/	390872
9	(national health service* or nhs*).ti,ab,in.	273686
10	(english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab.	50283
11	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jw,in.	2463828
12	(bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))).ti,ab,in.	1759486
13	(bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab,in.	70902
14	(aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab,in.	259101
15	(armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab,in.	34149
16	or/8-15	3092222
17	(exp africa/ or exp americas/ or exp antarctic regions/ or exp arctic regions/ or exp asia/ or exp oceania/) not (exp great britain/ or europe/)	3342884
18	16 not 17	2926695
19	7 and 18	91

Revised search strategy

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 1946 to September 15, 2023
15th September 2023

#	Searches	Results
1	("digital* health" or **"health technolog*" or "health and care technolog*"** or telecare or teleconsultation* or telehealth or tele-health or telemedicine or tele-medicine or ehealth or e-health or "computer based technolog*" or "mobile health" or "mobile medicine" or "mobile technology" or "remote consultation*" or "remote health" or "remote medicine" or "remote monitoring" or "remote rehabilitation*" or "technology enabled care" or "virtual health" or "virtual medicine" or "virtual rehabilitation*" or "online consultation*" or mhealth or m-health or telecoaching or teledentistry or telemonitoring or telepathology or teleradiology or telerehabilitation* or tele-rehabilitation*).ti.	36100
2	(framework* or taxonom* or classif* or defin* or standards).ti.	291988
3	1 and 2	635
4	(framework* or taxonom*).ab. /freq=2	98962

5	1 and 4	715
6	3 or 5	1087
7	limit 6 to english language	1051
8	exp Great Britain/	391055
9	(national health service* or nhs*).ti,ab,in.	274470
10	(english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab.	50466
11	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jw,in.	2468428
12	(bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))).ti,ab,in.	1763677
13	(bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab,in.	71087
14	(aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab,in.	259737
15	(armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab,in.	34245
16	or/8-15	3098021
17	(exp africa/ or exp americas/ or exp antarctic regions/ or exp arctic regions/ or exp asia/ or exp oceania/) not (exp great britain/ or europe/)	3346809
18	16 not 17	2932056
19	7 and 18	193
20	limit 19 to yr="2016 -Current"	152

Appendix 4: Practical use case description examples (From Rouleau et al, 2023)

"Use case 1: Using the Consolidated Framework for Implementation Research to identify barriers and facilitators to implementation, informing implementation outcomes Use case 1.1. Hadjistavropoulos et al. [70] conducted a process evaluation to identify barriers and facilitators that influenced the implementation of an internet-delivered cognitive behavior therapy (ICBT) across seven community mental health clinics. The ICBT targeted patients suffering from anxiety and depression and it was implemented for an average of two-years. The ICBT course includes five online core lessons (text-based with visual images) delivered over 8 weeks. In the meantime, patients could contact therapists by secure email for 8 weeks and they got email responses from therapists once a week. If needed, the therapists spent 15-20 minutes per week with patients (on phone calls).

Authors utilized CFIR to identify what factors impacted implementation and those that could impact future uptake of ICBT and its sustainability. In doing so, they used a survey administered to managers and therapists (survey available in the paper). The findings showed that ICBT characteristics (e.g., relative advantage, quality of the program, evidence underlying the intervention) and implementation process facilitated the endeavor while inner setting components (e.g., limited resources, face-to-face care as a priority, readiness for implementation, implementation climate) were identified as the main barriers impacting implementation. Authors reported potential strategies that can be deployed to improve implementation efforts, such as personalizing the ICBT intervention, better integration of ICBT in therapist's workflow, and reorganizing the model of delivering the intervention (e.g., involve mental primary care clinics).

Use case 1.2. Robins et al. [71] aimed to identify barriers and facilitators (determinants) to the implementation of an Electronic Communications and Home Blood Pressure Monitoring which integrated a pharmacist intensifying the blood pressure management strategies through web-messaging with patients. The CFIR was used in combination with the Chronic Care Model to identify what was influencing implementation in community settings so that adaptations to the DHI could be made. The assessment of determinants was gathered through interviews among physicians, medical assistants, licensed practice nurses, pharmacists, and patients. Barriers of implementation included the difficulty of integrating an unfamiliar pharmacist into the healthcare team (when there is no pharmacist in the "regular" team), concerns about the functioning of the collaborative practice (especially between physicians and pharmacists), lack of implementation readiness and implementation climate, limited resources (technological, financial and human), clinicians' concerns to using the blood pressure management protocol. The sustainability of such an intervention was raised as a concern. Facilitators of implementation included the perceived advantage of the DHI in improving quality of care, empowering patients, offering additional support to patients, saving staff time, and collaborative care benefits. This highlighted the need to adapt the DHIs by addressing those barriers, for example, by looking for additional technological options for ensuring secure and synchronous communication between patient and pharmacist when the electronic health record is not available. Mechanisms to support sustainability can target incentives that value and reward team-based care models such as pay-for-performance initiative."

"Use case 2.2. Koot et al. [73] conducted a quantitative evaluation of a mobile lifestyle management program for people with type 2 diabetes mellitus as an add-on to standard care aimed to assess the potential effectiveness and feasibility of the intervention. This program encompassed two components: online lessons and self-reporting, that were offered on two different online platforms. The RE-AIM was used to frame the evaluation, guide implementation planning, and inform data collection and analysis. Specifically, the findings showed statistically significant improvements for HbA1c (–1.3 percentage points, P<.001) that were greater among those who logged their weight more often (P=.007)(effectiveness outcome). Engagement in the intervention was higher in the first week and decreased over time (implementation dimension).

13.2 % of all patients approached for the study consented to participate (reach dimension). The authors did recommend to evaluate the effectiveness of this intervention (through randomized trial) based on promising results on health outcomes. However, those results can inform future evaluation in, for example, proactively targeting the population to whom referring the intervention (i.e improving "reach"), and identifying strategies to improve engagement over time such as making available the online lessons on the same platform than the self-reporting component of the intervention. One potential benefit of using this framework would be to collect data across RE-AIM dimensions in order to triangulate outcomes to understand the reason(s) for the observed effect."

These practical use case descriptions can be created for individual or multiple evaluations and used to disseminate the main contexts and findings from evaluations. The following table has been created to reflect the main elements that we found in the case descriptions above and can be used as a template.

Content	Evaluation Description
1) Function of the TEC	
2) Setting	
3) Target user(s)	
4) Intended outcomes	
5) Type of evaluation (e.g. process evaluation, impact evaluation, economic evaluation)	
6) Methods used (e.g. patient surveys, staff interviews, quantitative analysis of routine data etc.)	
7) Theories, models, or frameworks (TMFs) used (e.g. CFIR, NICE ESF, NASSS, RE-AIM)	
8) What the TMFs were used for (e.g. 'frame the evaluation, guide implementation planning, and inform data collection and analysis')	
9) Aims of the evaluation (e.g. 'assess the potential effectiveness and feasibility', 'identify barriers and facilitators (determinants) to the implementation', assess efficiencies etc.)	
10) Main findings	
11) Potential/actual use of evaluation findings (e.g. 'results can inform future evaluation in, for example, proactively targeting the population')	
12) Recommendations for practice	
13) Recommendations for future evaluation	

Appendix 5 The NASSS-CAT Tool: Project Version

NASSS-CAT (PROJECT VERSION)

FOR MONITORING PROJECT COMPLEXITY OVER TIME

This version of the NASSS-CAT is intended to be used when you are setting up and running a specific project to implement a new technology in a health or care setting. You may be asked to complete it more than once as the project unfolds. Score one point for every 'agree' answer and add up the orange column. In the blue column, tick if you think this issue is going to get <u>more</u> complex in the next phase of the project. Note: this tool will only give you a semi-quantitative estimate because some aspects of a project will be more important than others.

	Agree	*Disagree*	*Not applicable or don't know*	*Likely to get more complex in next phase*
STRATEGIC COMPLEXITIES				
1. The vision and benefits for the project are not yet clear				
2. The fit between this technology and the organisation's mission and strategy is poor				
3. The business case for the work is unclear or contested				
4. The scope of the project is unclear or contested				
5. The work will have major knock-ons for other key projects and business-as-usual operations				
6. Success criteria are not yet explicitly set out and agreed by key stakeholders				
7. The project's success could be threatened by external changes that impact on the organisation				
TOTAL STRATEGIC COMPLEXITY SCORE	/7			/7

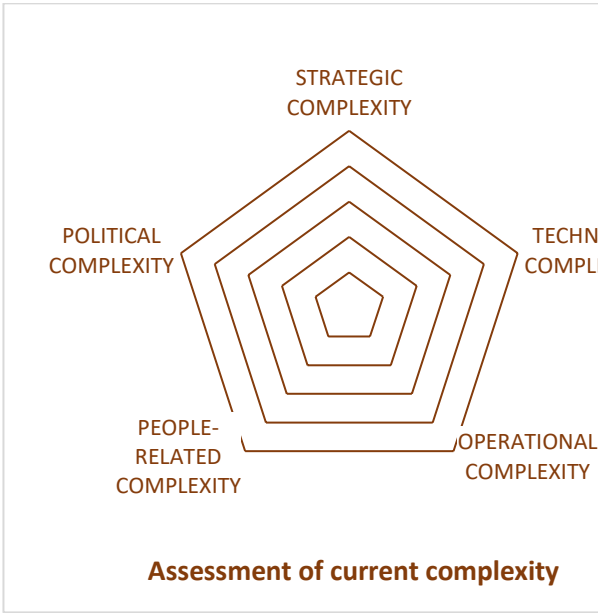
	Agree	*Disagree*	*Not applicable or don't know*	*Likely to get more complex in next phase*
TECHNICAL COMPLEXITIES				
1. The technology does not yet exist in a robust and dependable form				
2. The technology is unfamiliar to the project team				
3. The technology supply chain is not yet in place				
4. The technology cannot be installed until the system is upgraded (e.g. hardware, bandwidth)				
5. A key technology needs to be installed across multiple technical systems to achieve 'integration'				
6. Introducing the technology will require significant changes in care pathways and organisational routines				
7. Quality standards and regulatory requirements for using the technology in a health/care setting have not been fully defined (or key stakeholders don't know about them or accept them)				
TOTAL TECHNICAL COMPLEXITY SCORE	/7			/7

	Agree	*Disagree*	*Not applicable or don't know*	*Likely to get more complex in next phase*
OPERATIONAL COMPLEXITIES				
1. A schedule and resource plan have not yet been defined				
2. The pace of the project (time to achieve key goals and milestones) seems unachievable				
3. The budget is insufficient for the task or there is limited flexibility in how the budget can be used				
4. Resources (e.g. test facilities, equipment) may not be available when needed				
5. Evaluation measures and metrics have not yet been agreed				
6. Accurate, timely and comprehensive data reporting will be difficult or impossible				
7. New management tools and data sources will be needed to guide, monitor and evaluate the project				
TOTAL OPERATIONAL COMPLEXITY SCORE	*/7*			*/7*

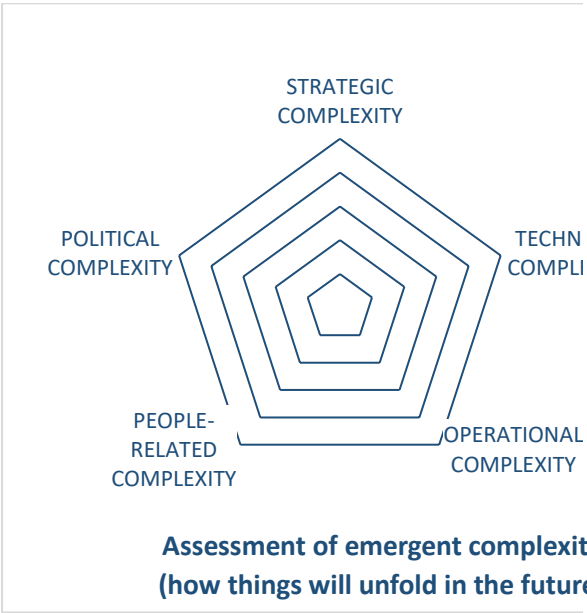
	Agree	*Disagree*	*Not applicable or don't know*	*Likely to get more complex in next phase*
PEOPLE-RELATED COMPLEXITIES				
1. The people leading the project are inexperienced in this kind of work				
2. The people leading the project do not have adequate control over project staff (e.g. no direct reporting)				
3. There are not yet sufficient people with the right skills available to participate in the project.				
4. There are no key people who are wholly allocated to the work for the project				
5. Lines of responsibility for tasks and deliverables are not yet defined				
6. Team members have limited confidence in the technology or do not fully understand how to use it				
7. Team members have limited motivation and are not yet functioning well as a team				
TOTAL PEOPLE-RELATED COMPLEXITIES	*/7*			*/7*

	Agree	*Disagree*	*Not applicable or don't know*	*Likely to get more complex in next phase*
"POLITICAL" COMPLEXITIES				
1. The work does not have a senior sponsor in the organisation who recognises its importance and helps negotiate its progress				
2. The senior management team in the relevant department does not fully support the work				
3. Substantial work will be needed to bring people on board and develop a shared vision for the change				
4. People beyond the core team don't understand the project or have unrealistic expectations for it				
5. People beyond the project team don't support the project or are not aligned or have insufficient time				
6. The core team does not have the authority to make decisions				
7. The work will require cooperation across sectors (e.g. health / social care)				
TOTAL "POLITICAL" COMPLEXITY SCORE	/7			/7

Plot your scores on the radar charts below to get a quick visualisation of the different complexities as assessed by you. The one on the left is your assessment of current complexity (orange columns above); on the right is your assessment of emergent complexity (blue columns above). Compare your radar charts with those made by your colleagues. Do your charts look the same? If not, where are the discrepancies and what explains these?



Assessment of current complexity



Assessment of emergent complexity (how things will unfold in the future)

Appendix 6: Theory development

There are many ways of developing an intervention theory. However, for a successful evaluation, the main purpose of an intervention theory is to understand what information is needed. A theory-based evaluation will help to explain why interventions work or don't work, who they work for, in what contexts and why. The theory will also help to provide early information about whether the intervention is likely to achieve the anticipated long-term outcomes by creating a causal chain of expectations and assumptions about inputs, activities, outputs, and initial outcomes. All interventions have underlying theory, which is often not explicitly stated. It is the evaluators' job to surface the theory, refine and test it.

Below is a simple textual logic model that can be used to map out the expectations and assumptions that should be the focus of the evaluation. It is important to record the expected relationships between the different elements, e.g. why should certain outputs lead to a specific intermediate outcome? The logic model should describe relationships, rather than being a catalogue of disconnected items. It can be useful to start with either the planned activities or expected outcomes.

Simple Textual Logic Model

INPUTS	ACTIVITIES	OUTPUTS	INTERMEDIATE OUTCOMES	LONG-TERM OUTCOMES

Inputs: are sometimes called resources. They can include such things as human, financial, and organisational resources.

Activities: are the actions required for the programme to happen. These can be the ways that technologies are deployed, associated processes, tools etc.

Outputs: are the products of the activities. For instance, these can be measured by the number of people using a particular technology, or the ways that they use it.

Intermediate outcomes: are changes that the intervention brings about. This could be different behaviour, changes in wellbeing, changes in skills or knowledge

Long-term outcomes: are changes resulting from the intervention that can take longer to be observed. For instance, these can be reductions in emergency hospital admissions, reduced mortality, maintaining independence for longer etc.

Some other approaches for theory development can be used:

- Theories of Change (TOCs)
- Logframes
- Realist matrices
- Outcomes hierarchies

The **'Better Evaluation' Website** has guidance and templates for several approaches.

https://www.betterevaluation.org/frameworks-guides/rainbow-framework/define/develop-programme-theory-theory-change

Appendix 7: The NICE Evidence Standards Framework for Digital Health Technologies (Updated 9th August 2022)

The framework can be downloaded here:

https://www.nice.org.uk/corporate/ecd7

Appendix 8: Budget Impact Analysis (BIA)

Budget impact analysis: health economic studies

How to use a budget impact analysis to evaluate your digital health product

https://www.gov.uk/guidance/budget-impact-analysis-health-economic-studies

Part of a collection of guidance on evaluating digital health products.

From: Office for Health Improvement and Disparities

Published: 28th January 2021

GOV.UK

Guidance

Budget impact analysis: health economic studies

How to use a budget impact analysis to evaluate your digital health product.

From: Office for Health Improvement and Disparities (/government/organisations/office-for-health-improvement-and-disparities)

Published 28 January 2021

Contents

This page is part of a collection of guidance on evaluating digital health products (https://www.gov.uk/government/collections/evaluating-digital-health-products).

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Related content

Cost consequence analysis: health economic studies (/guidance/cost-consequence-analysis-health-economic-studies)

Feasibility study (/guidance/feasibility-study)

Multiphase optimisation strategy (MOST) (/guidance/multiphase-optimization-strategy-

health expenditure of the budget holder (for example, the healthcare system) as a result of implementing your digital product.

BIA can be conducted:

- on its own – for example, to assess how affordable your product is likely to be, given potential budget constraints
- alongside a health economic evaluation – for example, to help decision makers assess the financial consequences of recommending your product for the healthcare system

BIA often complements health economic evaluations, but it has a distinct focus. BIA:

- often takes the budget holder perspective
- only includes costs and any savings that might accrue
- evaluates affordability not value for money

What to use it for

Use a BIA when:

- you want to assess the likely financial impact of your product before you implement it
- you need to work out whether your product will be affordable within the decision maker's budget constraints if it is recommended for use

Pros

Advantages of BIA include:

- it helps you to understand costs both incurred and saved by implementing your product
- it gives an estimate of the impact of your product on the decision maker's budget

Cons

Drawbacks of BIA include:

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Micro-randomised trial (/guidance/micro-randomised-trial)

Analysis of routinely collected data: descriptive studies (/guidance/analysis-of-routinely-collected-data-descriptive-studies)

Collection

Evaluating digital health products (/government/collections/evaluating-digital-health-products)

- it cannot tell you whether your product is good value for money or not
- it usually excludes costs from changes in effects that cannot be monetised, such as benefits captured by clinical measures

How to carry out a budget impact analysis

BIA typically involves the following steps:

1. Specify the target population

Start by working out what population is likely to be impacted by the new product. This includes:

- estimating the population size, which usually corresponds to the number of individuals with the relevant disease or condition (prevalence) and the number of new cases (incidence) that require treatment and are likely to benefit from your product
- accounting for potential untreated individuals who may decide to seek treatment after you product is made available
- breaking down the population by disease severity or stage as a way of carrying out BIA for population subgroups – and recognising that the proportion of individuals at different stages can change over time as your product is being adopted

2. Set the boundaries of the analysis

You will need to decide the timescale for your impact analysis. This is the duration over which you will measure changes to health expenditure and cost savings.

The duration you choose will depend on the budget holder’s planning timescale and is often not related to the duration of the disease. This means it is important to carefully consider whether the changes in expenditure and cost savings are likely or not to

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3. Determine treatment mix

An important element of BIA is determining any changes to treatment mix as a result of making your product available. This will depend on:

- the uptake of your product
- whether your product replaces or supplements current options

For example, if your product replaces an existing one, you will need to make an assumption about the costs saved by displacing the existing product.

4. Estimate product and disease-related costs

To estimate the costs associated with your product you should follow general considerations for measuring costs in health economic evaluations (https://www.gov.uk/guidance/economic-evaluation-health-economic-studies). However, relevant costs for BIA may differ because it often takes a more restrictive budget holder perspective. For example, BIA is unlikely to include development costs or costs to the patient.

You should also consider changes to disease-related costs if your product is likely to affect these. For example, if your product helps patients prevent heart conditions, then the avoided costs of treating those conditions should be considered in BIA. This is particularly relevant when your product is expected to have an immediate impact on disease-related expenditure, which may be the case with acute conditions.

5. Report the results

Budget impact results should be reported in a disaggregated way – that is, with main cost components reported individually. This will enable the budget holder to understand the relative weight of each cost component to the total cost impact. The budget impact should also be reported separately for each year considered in the analysis.

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BIA studies should include a set of sensitivity analysis scenarios (see ‘Sensitivity analysis’ in Analyse your data: evaluating digital health products (https://www.gov.uk/guidance/analyse-your-data-evaluating-digital-health-products)). These scenarios allow you to understand the impact of making alternative assumptions about important aspects of the study on the budget impact assessment. For example, it may be helpful for you to understand how the budget impact changes according to alternative assumptions about population size, treatment mix and cost measurements.

Example: Digital diabetes and hypertension care

See Nordyke and others (2019): Estimating the impact of novel digital therapeutics in type-2 diabetes and hypertension: health economic analysis (https://www.jmir.org/2019/10/e15814/).

This study explores the economic impact of digital behavioural interventions (mobile apps) for managing patients with high-cost cardiometabolic diseases, such as type-2 diabetes and hypertension. The analysis was conducted from the viewpoint of the US commercial payer. A 3-year timescale was chosen, taking into account significant enrolee turnover and the fact that engagement with and impact of these apps tend to wane over time.

The population expected to benefit from the apps included individuals with active disease (either type-2 diabetes or hypertension) who were receiving conventional pharmacological treatment.

The digital interventions were expected to supplement conventional pharmacological treatments, so the budget assessment focused on the cost implications of adding the behavioural intervention to the existing treatment mix. The study allowed for potential drop-out (treatment discontinuation) over the 3-year period.

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- cost of implementing the digital interventions
- medications costs – including any changes to pharmacological treatments as a result of adopting the behavioural interventions
- cost savings associated with likely reduction in cardiovascular events and related hospitalisations

The study found that the digital health interventions would lead to an estimated cost saving of:

- $145 per patient, per month, for the type-2 diabetes population
- $97 per patient, per month, for hypertensive patients

This would represent a reduction of 22% and 29% in total health expenditures compared to the conventional pharmacological care pathways. Any assumed savings, such as the proposed cost savings due to reduction in cardiovascular disease-related hospitalisations, should be examined in sensitivity analysis (not done in this study).

More information and resources

NICE Evidence Standards Framework for Digital Health Technologies (2019) – Cost Consequences and Budget Impact Analyses and Data Sources (https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/budget-impact-guide.pdf). This guide describes the principles of budget impact analysis (BIA) as part of NICE's evidence standards framework for digital health technologies.

NICE Budget Impact template (https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/Company-budget-impact-analysis-submission.docx). This is the recommended budget assessment template document for submitting BIA to NICE as part of its health technology assessment programme.

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do/Into-practice/assessing-resource-impact-process-manual-ta-hst.pdf) – technology appraisal and highly specialised technologies (2017). This manual describes the processes involved in assessing resource impact of health technologies.

Sullivan and others (2012): Budget impact analysis – principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force (https://www.sciencedirect.com/science/article/pii/S1098301513042356). The study provides a methods guide for conducting BIA. This includes methodological insights on the analytic framework for BIA, recommendations of data sources to inform budget assessments and guidance on reporting standards.

Mauskopf and Earnshaw (2016): A methodological review of US budget impact models for new drugs (https://pubmed.ncbi.nlm.nih.gov/27334107/). This study critically assesses the extent to which published BIA studies follow recommended methodological guidelines. While the review covered budget assessment studies that inform recommendations about new drugs, the findings of the review are fully relevant to anyone conducting BIA of novel digital products.

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