NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

EVIDENCE STANDARDS FRAMEWORK FOR DIGITAL HEALTH TECHNOLOGIES

Summary of comments and feedback from phase 2 survey

March 2021

## Introduction

Since its publication in December 2018, the evidence standards framework (ESF) has gained a reputation as a trusted source of advice on what evidence to produce for digital health technologies.

NICE published a survey on its website in late 2019 to gather information on how to make the framework easier to use, clearer, and what tools should be provided to help stakeholders.

Feedback was gathered from both semi-structured survey questionnaires and through informal stakeholder interviews. This report summarises the responses to the survey.

## Summary of responses

There were 52 complete responses (see [summary analysis](#_Summary_analysis)) from stakeholders across industry, academia, patients and clinical experts. Most of the survey respondents had used the framework and overall user experience was positive.

Additional feedback was obtained from interviews with a range of stakeholders including digital health specialists, service design consultants and collaborators from partner organisations.

The [main themes of the feedback](#table1) (based on free text and verbal responses), and the actions taken by NICE in response to each theme, are summarised in the following table.

### Main themes from the feedback

| Themes | Comment | Action taken |
| --- | --- | --- |
| Resources, education and training | Signpost developers to knowledge resources for evidence generation, research funding and to organisations producing related guidance.  Lack of training on economic analysis for small and medium-sized enterprises.  Challenges in executing economic analysis.  Lack of wider education during early implementation. | Additional text has been added to the main document signposting to relevant knowledge resources. |
| Scope | Additional clarity about what is covered or not by the ESF, such as confidentiality and data storage.  Lack of clarity in the ESF on how it differs from the Digital Assessment Questionnaire (DAQ). | The user guide has been reviewed for clarity on how the ESF is designed to work with NHSX’s Digital Technology Assessment Criteria (DTAC). The DTAC replaces the DAQ. |
| Mapping ESF to the 2017 European medical devices regulation (MDR) | Need to describe how the ESF relates to the MDR. | NICE commissioned the Newcastle upon Tyne Hospitals NHS Foundation Trust External Assessment Centre to produce a mapping document to describe how the evidence requirements for MDR can be used by developers to meet ESF evidence requirements. |
| Regulatory requirements | Guidance on digital health technologies (DHTs) that are not considered medical devices. | We have added further explanation to the descriptions of the functional categories to show where non-CE marked medical devices are expected to fit. |
| Future development: engagement | A need to engage stakeholders from commissioning and social care organisations. | We have been unable to identify the best ways to engage with social care organisations and commissioners in the current update of the ESF. This will continue to be a priority in future iterations of the ESF. |
| Evidence sources and requirements | Need guidance on use of real-world evidence and non-randomised controlled trial designs.  Lack of emphasis about other non-randomised controlled study designs.  Lack of evidence that DHT does not exacerbate inequalities. | NICE will continue to develop our processes to fully understand and utilise the potential of real-world evidence and innovative trial designs in the ESF. |
| Risk and functional classification | Refinement of risk classification:  Tier 1 too broad.  Slight overlap between tier 2 and tier 3a.  Lack of clarity on classifying combination products. | We have added to the descriptions of functional classification to be clearer about which technologies fit into which categories. |
| General | Transferability of approach to other countries.  Costs associated with evidence assessment. | The ESF is has been written for the UK health and social care system. Some of the principles may be transferable to other countries but this is outside of the remit for the current ESF.  Evidence assessment is expected to be done by, or on behalf of, health and social care commissioners. Any costs associated with this are outside of NICE’s remit. |
| Evidence of effectiveness | A need for increased clarity. | The ESF document and the user guide have been reviewed to improve clarity. |
| Evidence of effectiveness | Stronger evidence requirements for tier 1. | Feedback from stakeholders during initial review of the evidence levels did not indicate that the tier 1 evidence requirements were too low. We will continue to monitor feedback and will reconsider evidence levels if overall feedback indicates that this is needed. |
| Evidence of effectiveness | Importance of frontline user sign-off. | Health or social care professional sign-off is already included. |
| Evidence of effectiveness | Intended users need to be involved in testing. | We will continue to consider the best way to include user involvement. Currently, DHT owners are required to show user satisfaction as a minimal requirement. |
| Evidence of effectiveness | Need additional standards for evaluating algorithms and diagnostic or advisory apps. | NHSx and the British Standards Institution are currently working on standards for artificial intelligence algorithms. When these are available, we will link to this work from the ESF.  Diagnostic DHTs are included in evidence tier C: interventions (formerly tier 3b). |
| Evidence of effectiveness | Should there be a staged/phased evidence requirement based on level of adoption? | The ESF is designed to be used at individual commissioning/purchasing decisions. The scale of adoption does not affect the level of evidence required. |
| Process | Who is validating the evidence requirements for each tier? | The evidence tiers were designed by NICE in collaboration with stakeholders including commissioners, medical technologies and DHT industry representatives, Academic Health Science Networks, academic experts and clinicians. |
| Process | Who should generate the data? | Evidence is generated by the DHT company. |
| Process | Who is evaluating the data? | Evidence is evaluated by the organisation making the commissioning/purchasing decision. |
| Process | How does the ESF link to decision making and adoption in NHS? | It is intended that the ESF will be used to inform purchasing/commissioning decisions in the UK health and social care system, including the NHS. The ESF sets out standards of evidence that a DHT should ideally meet in order to be used in the health and care system. |

## Summary analysis

The following tables summarise the responses to the structured questions from the 52 complete surveys.

To help us understand the answers you give, which of the following most closely matches your role in relation to digital healthcare?

|  |  |
| --- | --- |
| Options | Number of responses |
| I am a commercial developer, or work in market access, for digital health technologies | 17 |
| I use digital healthcare technologies in the management of my own health and wellbeing | 10 |
| I am a health or social care commissioner - I have commissioned digital health technologies in my work | - |
| I am a health or social care commissioner - I have not commissioned digital health technologies in my work | 1 |
| I am a health or social care worker (including healthcare professionals) - I prescribe digital health technologies in my work | 7 |
| I am a health or social care worker (including healthcare professionals) - I do not prescribe digital health technologies in my work | 6 |
| I am an academic with a professional interest in evaluating digital healthcare technologies | 19 |
| I work outside of the UK | 6 |
| None of these | 7 |

Are you aware of the evidence standards framework (ESF)? If so, to what extent are you using it and the supporting resources provided?

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| 1 – Not at all | 19 | 37 |
| 2 | 11 | 21 |
| 3 | 9 | 17 |
| 4 | 8 | 15 |
| 5 – To a great extent | 5 | 10 |

For what purpose have you used the evidence standards framework and its supporting resources to date?

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| For general information about expected evidence standards | 21 | 68 |
| To identify gaps in the evidence of a technology | 16 | 52 |
| To help develop evidence generation plans | 14 | 45 |
| To inform launch or marketing of a technology to NHS | 10 | 32 |
| To make a procurement or commissioning decision | - | - |
| Other | 3 | 10 |

How would you rate your overall experience of using the evidence standards framework and its supporting resources?

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| 1 - Poor | 2 | 8 |
| 2 | 2 | 8 |
| 3 | 11 | 42 |
| 4 | 9 | 35 |
| 5 - Excellent | 2 | 8 |

Did you find the evidence standards easy to find and access online?

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Yes | 23 | 90 |
| No | 3 | 10 |

Did you find the evidence standards in a format that is easy to use (viewable on tablets, multiple web browsers)?

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Yes | 23 | 74 |
| No | 8 | 26 |

Did you find the evidence standards sufficiently clear and easy to understand (in terms of language, structure etc.)?

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Yes | 23 | 74 |
| No | 8 | 26 |

Did you find the evidence standards suitable for your target audience?

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Yes | 17 | 57 |
| No | 13 | 43 |

Are you seeking any additional support in helping to apply the ESF, for example from Academic Health Science Networks?

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Yes | 7 | 58 |
| No | 5 | 42 |

Since the ESF’s release in March 2019, has your technology fitted into any of the below classifications? If so, which one(s)? Please select all that apply.

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Tier 1 (System services) | 7 | 10 |
| Tier 2 (Inform) | 8 | 12 |
| Tier 2 (Simple monitoring) | 5 | 7 |
| Tier 2 (Communicate) | 5 | 7 |
| Tier 3a (Preventative behaviour change) | 10 | 14 |
| Tier 3a (Self-manage) | 8 | 12 |
| Tier 3b (Treat) | 6 | 9 |
| Tier 3b (Active monitoring) | 6 | 9 |
| Tier 3b (Calculate) | 7 | 10 |
| Tier 3b (Diagnose) | 7 | 10 |
| Total number of technologies | 69 | - |
| Not applicable, I haven’t done this yet | 11 | - |

Which levels of risk have you identified when applying the ESF to your technology? Please select all that apply.

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| High risk | 6 | 19 |
| Low risk | 11 | 34 |
| Not sure | 5 | 16 |
| None | 2 | 6 |
| Not applicable, I haven’t done this yet | 13 | 41 |

Which levels of economic analysis have been appropriate when applying the ESF to your technology? Please select all that apply.

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Basic | 4 | 13 |
| Low financial commitment | 8 | 25 |
| High financial commitment | 2 | 6 |
| Not sure | 3 | 9 |
| Not applicable, I haven’t done this yet | 18 | 56 |

Which of these did you use in supporting the application of the ESF, and how useful did you find them?

#### **User guide**

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Very useful | 7 | 24 |
| Useful | 11 | 38 |
| Not useful | 1 | 3 |
| No opinion / Not used | 10 | 35 |

#### **Budget impact template**

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Very useful | 4 | 13 |
| Useful | 8 | 27 |
| Not useful | 3 | 10 |
| No opinion / Not used | 15 | 50 |

#### **Budget impact guides**

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Very useful | 3 | 10 |
| Useful | 7 | 24 |
| Not useful | 5 | 17 |
| No opinion / Not used | 14 | 48 |

#### **Functional classification case studies**

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Very useful | 5 | 17 |
| Useful | 11 | 38 |
| Not useful | 2 | 7 |
| No opinion / Not used | 11 | 38 |

#### **Effectiveness and economic impact case studies**

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Very useful | 3 | 10 |
| Useful | 13 | 45 |
| Not useful | 3 | 10 |
| No opinion / Not used | 10 | 35 |

If you used the budget impact template: Thinking specifically about the budget impact template, how did you use this?

|  |  |  |
| --- | --- | --- |
| Options | Number | % |
| Completed the template myself for my work | 3 | 21 |
| Worked with health economist to complete template | 2 | 14 |
| Reviewed a completed template for my company/colleague | 1 | 7 |
| Other | 8 | 57 |

Which of the following would you prioritise as a future development for the ESF or which would you gain the most benefit from and why? (1 being the highest and 6 the lowest, as well as anything you think should be included)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Development | 1 | 2 | 3 | 4 | 5 | 6 |
| A more user-friendly version of the ESF (e.g. an online tool to classify DHTs and suggest paths to evidence generation) | 11 | 11 | 6 | 3 | 6 | 1 |
| Critical appraisal tools (such as check lists for systematic and qualitative reviews) | 10 | 6 | 12 | 6 | 4 | 1 |
| An ESF checklist to aid the quick classification of a DHT to the appropriate evidence for effectiveness tier | 8 | 7 | 9 | 9 | 6 | 0 |
| Aligning the ESF to the EU medical devices directive | 12 | 7 | 5 | 5 | 5 | 3 |
| Develop linked budget impact and cost consequence templates | 4 | 9 | 7 | 5 | 7 | 4 |
| Other | 2 | 2 | - | 3 | - | 3 |

Do you have any requirements that have not been covered?

|  |  |
| --- | --- |
| Yes, n (%) | 11 (23%) |
| No, n (%) | 36 (77%) |