

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

EVIDENCE STANDARDS FRAMEWORK FOR DIGITAL HEALTH TECHNOLOGIES

Summary of comments and feedback

March 2019

Introduction

This report summarises the responses to a survey on the NICE website about the evidence standards framework for digital health technologies (DHTs) through which stakeholders were invited to complete a semi-structured questionnaire.

On 10 December 2018, the evidence standards framework, an FAQ document and a budget impact Excel tool were published on the NICE website. MedCity coordinated extensive marketing and communication and NICE sent a link to the landing page and survey to 210 individual stakeholders.

A report is being developed which describes the methods used to develop the evidence standards framework.

Summary of responses

There were 46 complete responses (see [summary analysis](#)), 168 incomplete survey responses (providing information of very limited use) and 7 separate written responses. A wide and representative range of stakeholders submitted responses including companies and industry associations, NHS clinicians and managers, digital health academics and national health and care system organisations.

The framework was generally welcomed and most respondents agreed with the content and methods used. Because of this, and the scope and timeline of development, only minor changes were made to the framework itself. The FAQ document was updated and repurposed as a user guide. Other feedback from the survey will inform future work.

Table 1 summarises the main themes of the survey feedback and the actions taken in response.

Table 1 Summary of stakeholder feedback and action taken

Theme	Issues raised by respondents	Action taken
Editorial/presentation	Terms are not widely understood. Aims and context are unclear and inconsistent between the main framework document and FAQs. Clarification on how to use the functional classification and evidence tables. Overlap/duplication with other standards.	A glossary has been added and will be linked to from the text. The text of the documents has been improved for consistency. Additional text in the main document summarises the aims and context. The FAQ has been repurposed as a user guide and further explanatory text added, with links to other relevant standards/regulatory requirements.
Economic impact evidence standards	Limited economic evidence available for DHTs. Lack of capacity/capability for economic analysis in the system generally.	An additional level (basic) has been added for low impact DHTs which are undergoing local service evaluation and for which a budget impact analysis (rather than any further economic analysis) is needed. The supporting resources now include a short guide to economic analysis by the Newcastle and York external assessment centre.
Future development: engagement	Lack of recognition of widespread use of DHTs in social care. Patient and public involvement.	Listed in user guide as future priority areas identified by stakeholders.
Future development: implementation	Evidence burden on SMEs. Place in market access arrangements. Place in compliance regime for DHTs.	Listed in user guide as future priority areas identified by stakeholders.
Methods	Dynamic nature of DHTs; crossover between tiers; refinement of risk concept; further reference to real-world data and evidence; further refinement of approach to artificial intelligence.	Listed in user guide as future priority areas identified by stakeholders.

Summary analysis

This table summarises 46 complete Snap Survey responses submitted between 10 December 2018 and 14 January 2019.

Table 2 Complete survey responses

No.	Question												
Purpose and scope													
1	Is it clear:												
a	what these standards are for? (Y/N checkbox)												
	<table border="1"><thead><tr><th></th><th>Number</th><th>%</th></tr></thead><tbody><tr><td>Yes</td><td>43</td><td>93</td></tr><tr><td>No</td><td>3</td><td>7</td></tr><tr><td>Blank</td><td>0</td><td>0</td></tr></tbody></table>		Number	%	Yes	43	93	No	3	7	Blank	0	0
	Number	%											
Yes	43	93											
No	3	7											
Blank	0	0											
b	who they are aimed at? (Y/N checkbox)												
	<table border="1"><thead><tr><th></th><th>Number</th><th>%</th></tr></thead><tbody><tr><td>Yes</td><td>38</td><td>83</td></tr><tr><td>No</td><td>7</td><td>15</td></tr><tr><td>Blank</td><td>1</td><td>2</td></tr></tbody></table>		Number	%	Yes	38	83	No	7	15	Blank	1	2
	Number	%											
Yes	38	83											
No	7	15											
Blank	1	2											
c	how to use them? (Y/N checkbox)												
	<table border="1"><thead><tr><th></th><th>Number</th><th>%</th></tr></thead><tbody><tr><td>Yes</td><td>37</td><td>80</td></tr><tr><td>No</td><td>8</td><td>17</td></tr><tr><td>Blank</td><td>1</td><td>2</td></tr></tbody></table>		Number	%	Yes	37	80	No	8	17	Blank	1	2
	Number	%											
Yes	37	80											
No	8	17											
Blank	1	2											
2	Are there any terms, definitions or aspects of the document that are not easily understood? (Y/N checkbox)												
	<table border="1"><thead><tr><th></th><th>Number</th><th>%</th></tr></thead><tbody><tr><td>Yes</td><td>17</td><td>37</td></tr><tr><td>No</td><td>29</td><td>63</td></tr><tr><td>Blank</td><td>0</td><td>0</td></tr></tbody></table>		Number	%	Yes	17	37	No	29	63	Blank	0	0
	Number	%											
Yes	17	37											
No	29	63											
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3	Is the scope of these standards clear, in terms of:												
a	what technologies are within scope? (Y/N checkbox)												
	<table border="1"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Yes</td><td>36</td><td>78</td></tr> <tr> <td>No</td><td>10</td><td>22</td></tr> <tr> <td>Blank</td><td>0</td><td>0</td></tr> </tbody> </table>		Number	%	Yes	36	78	No	10	22	Blank	0	0
	Number	%											
Yes	36	78											
No	10	22											
Blank	0	0											
b	what technologies are outside of scope? (Y/N checkbox)												
	<table border="1"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Yes</td><td>32</td><td>70</td></tr> <tr> <td>No</td><td>14</td><td>30</td></tr> <tr> <td>Blank</td><td>0</td><td>0</td></tr> </tbody> </table>		Number	%	Yes	32	70	No	14	30	Blank	0	0
	Number	%											
Yes	32	70											
No	14	30											
Blank	0	0											
c	how these evidence for effectiveness standards fit alongside other relevant standards such as the Digital Assessment Question? (Y/N checkbox)												
	<table border="1"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Yes</td><td>24</td><td>52</td></tr> <tr> <td>No</td><td>21</td><td>46</td></tr> <tr> <td>Blank</td><td>1</td><td>2</td></tr> </tbody> </table>		Number	%	Yes	24	52	No	21	46	Blank	1	2
	Number	%											
Yes	24	52											
No	21	46											
Blank	1	2											
4	Alongside the evidence standards framework we have published a FAQs document. Did you find the FAQs document useful? (Y/N checkbox)												
	<table border="1"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Yes</td><td>40</td><td>87</td></tr> <tr> <td>No</td><td>6</td><td>13</td></tr> <tr> <td>Blank</td><td>0</td><td>0</td></tr> </tbody> </table>		Number	%	Yes	40	87	No	6	13	Blank	0	0
	Number	%											
Yes	40	87											
No	6	13											
Blank	0	0											
Functional classification													
5	Can you think of any digital health technologies (DHTs) that do not fit within the functional classification? (Y/N checkbox)												
	<table border="1"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Yes</td><td>11</td><td>24</td></tr> <tr> <td>No</td><td>34</td><td>74</td></tr> <tr> <td>Blank</td><td>1</td><td>2</td></tr> </tbody> </table>		Number	%	Yes	11	24	No	34	74	Blank	1	2
	Number	%											
Yes	11	24											
No	34	74											
Blank	1	2											

6a	Is the proposed approach to artificial intelligence clear? (Y/N checkbox)		
b	Do you think this approach is appropriate? (Y/N checkbox)		
7a	The functional classification of DHTs uses the risk of harm to guide the level of evidence of effectiveness. Do you think that this approach is appropriate? (Y/N checkbox)		
b	Are there any other risk factors or considerations specific to digital healthcare that should influence the evidence of effectiveness requirements? (Y/N checkbox)		
8	To help use the functional classification, we have developed some contextual questions. Are the contextual questions helpful? (Y/N checkbox)		

Evidence standards for effectiveness of intended use																	
9	<p>Do you think that the levels of evidence for effectiveness for each evidence tier are about right, too low, or too high? Checkbox options:</p> <ul style="list-style-type: none"> • too high • about right • too low <table border="1"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Too high</td><td>11</td><td>24</td></tr> <tr> <td>About right</td><td>28</td><td>61</td></tr> <tr> <td>Too low</td><td>6</td><td>13</td></tr> <tr> <td>Blank</td><td>1</td><td>2</td></tr> </tbody> </table>			Number	%	Too high	11	24	About right	28	61	Too low	6	13	Blank	1	2
	Number	%															
Too high	11	24															
About right	28	61															
Too low	6	13															
Blank	1	2															
10	<p>In tiers 3a and 3b, there are requirements for research studies showing effectiveness. Are the types of studies described here appropriate? (Y/N checkbox)</p> <table border="1"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Yes</td><td>31</td><td>67</td></tr> <tr> <td>No</td><td>13</td><td>28</td></tr> <tr> <td>Blank</td><td>2</td><td>4</td></tr> </tbody> </table>			Number	%	Yes	31	67	No	13	28	Blank	2	4			
	Number	%															
Yes	31	67															
No	13	28															
Blank	2	4															
11	<p>Has the potential for DHTs to systematically collect real world data been recognised fully? (Y/N checkbox)</p> <table border="1"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Yes</td><td>18</td><td>39</td></tr> <tr> <td>No</td><td>25</td><td>54</td></tr> <tr> <td>Blank</td><td>3</td><td>7</td></tr> </tbody> </table>			Number	%	Yes	18	39	No	25	54	Blank	3	7			
	Number	%															
Yes	18	39															
No	25	54															
Blank	3	7															
Evidence standards for economic impact standards																	
12	<p>To demonstrate the DHT's economic impact on the UK health and social care system, do you think the economic standards are too high, about right, or too low? Checkbox options:</p> <ul style="list-style-type: none"> • too high • about right • too low <table border="1"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Too high</td><td>9</td><td>20</td></tr> <tr> <td>About right</td><td>29</td><td>63</td></tr> <tr> <td>Too low</td><td>4</td><td>9</td></tr> <tr> <td>Blank</td><td>4</td><td>9</td></tr> </tbody> </table>			Number	%	Too high	9	20	About right	29	63	Too low	4	9	Blank	4	9
	Number	%															
Too high	9	20															
About right	29	63															
Too low	4	9															
Blank	4	9															

13	<p>What are your thoughts on the term 'financial risk' to describe the factor determining the type of economic analysis required?</p> <p>Checkbox options:</p> <ul style="list-style-type: none"> • appropriate • not appropriate <table border="1" data-bbox="298 428 1389 592"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Appropriate</td><td>30</td><td>65</td></tr> <tr> <td>Not appropriate</td><td>13</td><td>28</td></tr> <tr> <td>Blank</td><td>3</td><td>7</td></tr> </tbody> </table>		Number	%	Appropriate	30	65	Not appropriate	13	28	Blank	3	7
	Number	%											
Appropriate	30	65											
Not appropriate	13	28											
Blank	3	7											
14a	<p>The standard for appropriate economic analysis (cost-consequence or cost-effectiveness) depends on whether the financial risk is low or high from the perspective of the payer. Does this make sense to you? (Y/N checkbox)</p> <table border="1" data-bbox="298 804 1389 968"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Yes</td><td>36</td><td>78</td></tr> <tr> <td>No</td><td>7</td><td>15</td></tr> <tr> <td>Blank</td><td>3</td><td>7</td></tr> </tbody> </table>		Number	%	Yes	36	78	No	7	15	Blank	3	7
	Number	%											
Yes	36	78											
No	7	15											
Blank	3	7											
b	<p>Do you think it would make more sense to have financial bands? (Y/N checkbox)</p> <table border="1" data-bbox="298 1096 1389 1260"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Yes</td><td>10</td><td>22</td></tr> <tr> <td>No</td><td>31</td><td>67</td></tr> <tr> <td>Blank</td><td>5</td><td>11</td></tr> </tbody> </table>		Number	%	Yes	10	22	No	31	67	Blank	5	11
	Number	%											
Yes	10	22											
No	31	67											
Blank	5	11											
Budget impact template													
15a	<p>Did you find the budget impact template easy to use? (Y/N check box)</p> <table border="1" data-bbox="298 1417 1389 1581"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Yes</td><td>22</td><td>48</td></tr> <tr> <td>No</td><td>16</td><td>35</td></tr> <tr> <td>Blank</td><td>8</td><td>17</td></tr> </tbody> </table>		Number	%	Yes	22	48	No	16	35	Blank	8	17
	Number	%											
Yes	22	48											
No	16	35											
Blank	8	17											
b	<p>Did you encounter any problems when using it? (Y/N check box)</p> <table border="1" data-bbox="298 1715 1389 1879"> <thead> <tr> <th></th><th>Number</th><th>%</th></tr> </thead> <tbody> <tr> <td>Yes</td><td>8</td><td>17</td></tr> <tr> <td>No</td><td>29</td><td>63</td></tr> <tr> <td>Blank</td><td>9</td><td>20</td></tr> </tbody> </table>		Number	%	Yes	8	17	No	29	63	Blank	9	20
	Number	%											
Yes	8	17											
No	29	63											
Blank	9	20											

Further resources									
16	We are developing the following resources to support users of the framework. Please tell us about the usefulness and relative priority of these :								
	Option	High priority		Medium priority		Low priority		Blank	
		N	%	N	%	N	%	N	%
Worked examples of completed functional classifications for selected digital health technologies	27	59	13	28	2	4	4	9	
Case studies illustrating the evidence base for selected digital health technologies	30	65	6	13	6	13	4	9	
Signposting to resources on study design to demonstrate effectiveness, and/or critical appraisal of published studies	17	37	19	41	6	13	4	9	
Worked example of assessing economic impact for selected digital health technologies	26	57	13	28	3	7	4	9	
Resources to help understand different types of economic evidence	11	24	22	48	9	20	4	9	
Signposting to sources of high quality information for use in economic analysis, such as population data	17	37	20	43	5	11	4	9	
Resources to help understand how to evaluate the quality of economic evidence	11	24	22	48	9	20	4	9	

	Signposting to organisations that can help in the design and funding of economic studies	7	15	22	48	13	28	4	9
	Suggestions for organisations to contact to help in developing budget impact inputs	7	15	19	41	16	35	4	9
About you									
17a	To help us understand the answers you have given, please select the options below that best describe your perspectives on digital healthcare (please select as many as appropriate):								
	Options (select all that are appropriate)	Number			%				
	I am a commercial developer, or work in market access, for digital health technologies	18			39				
	I am an academic with a professional interest in evaluating digital healthcare technologies	14			30				
	I use digital healthcare technologies in the management of my own health and wellbeing	9			20				
	I am a health or social care worker (including healthcare professionals) who prescribes digital healthcare technologies in my work	7			15				
	I am a health or social care commissioner	3			7				
	I work outside of the UK	2			4				

b	None of these (please describe your role)																						
	<table border="1"> <thead> <tr> <th>Responder</th><th>Feedback</th></tr> </thead> <tbody> <tr> <td>3</td><td>• Patient</td></tr> <tr> <td>6</td><td>• INHS Head of Electronic Engineering</td></tr> <tr> <td>16</td><td>• Digital project manager, social care</td></tr> <tr> <td>19</td><td>• Health information consultant</td></tr> <tr> <td>25</td><td>• NHS trust digital exemplar programme manager</td></tr> <tr> <td>32</td><td>• Digital health care strategy expert working in the NHS</td></tr> <tr> <td>34</td><td>• Care Quality Commission</td></tr> <tr> <td>37</td><td>• Library and Knowledge Services, Health Education England</td></tr> <tr> <td>41</td><td>• Department for International Trade (DIT)</td></tr> <tr> <td>43</td><td>• Diagnostics industry association</td></tr> </tbody> </table>	Responder	Feedback	3	• Patient	6	• INHS Head of Electronic Engineering	16	• Digital project manager, social care	19	• Health information consultant	25	• NHS trust digital exemplar programme manager	32	• Digital health care strategy expert working in the NHS	34	• Care Quality Commission	37	• Library and Knowledge Services, Health Education England	41	• Department for International Trade (DIT)	43	• Diagnostics industry association
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