

eHealth assessment criteria - Delphi process, Round 2

Finalising the assessment criteria

Thanks again for participating in the study and taking the time to fill Round 1 survey. This is the final step in finalising the list of assessment criteria based on your input. This final survey takes about 15 minutes to complete.

Why a second round?

The Delphi methodology is a consensus based process, it allows for reflection among participants, who are able to nuance and reconsider their opinion based on the anonymised opinions of others. Therefore, this final round aims to:

- confirm the definite exclusion of the criteria that did not meet the pre-defined consensus in Round 1 by corroborating experts' assessment of these criteria (most of these have been slightly reworded or expanded based on expert feedback in the first round)
- validate the relevance of the additional expert-suggested criteria that were deemed to be missing in the first round

A criteria is considered a must-have criteria only if 75% of the experts assess its relevance at 4 or 5 on the Likert scale.

Hence, the objectives of Round 2 survey are:

01	Criteria that did not meet consensus	• Final assessment of the 17 criteria that did not meet the predefined 75% consensus in Round 1 • These have sometimes been slightly reworded or expanded based on expert feedback in Round 1 • Experts will not have to reassess risk levels again
02	Additional criteria	• Assessment of the additional criteria suggested by the experts in Round 1 • 9 new criteria to assess and to define the respective risk level

Reminder: This project focuses solely on assessing **patient-facing eHealth tools**, including self-management tools and remote eHealth solutions, rather than tools used within and between care providers (e.g., Electronic Health Records), digital biomarkers, or health data analytics systems used at population level.

Disclaimer: This research project is intended for educational purposes only and is not intended as legal advice. Payers have differing coverage and reimbursement policies. Laws, regulations, and health insurance policies concerning coverage, coding, and reimbursement are complex and are evolving rapidly. For legal advice, please consult with legal counsel.

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Final assessment of the criteria that did not meet expert consensus in Round 1

*Most of the criteria have been slightly reworded or expanded based on the experts' feedback in Round 1. Any **changes have been marked in bold** to make it easy for you to spot them.*

* 1.1.4. The tool allows the possibility to give instant feedback to the developers (e.g., provider messaging to report technical issues or errors, **inaccuracies or inconsistent workflows**)

1 <i>I suggest this criterion is excluded</i>	2	3	4	5 <i>This criterion is extremely relevant</i>	I can't assess
★	★	★	★	★	○

* 1.2.2.b. The tool considers multiple health issues and related ones, and sufficiently addresses them to help meet the intended purpose **without overwhelming the user (i.e. consider comorbidities, and features that may improve overall quality of life, e.g. adding breathing exercises in a remote patient monitoring tool for lung cancer patients)**

1 <i>I suggest this criterion is excluded</i>	2	3	4	5 <i>This criterion is extremely relevant</i>	I can't assess
★	★	★	★	★	○

* 1.3.1.c. There is sufficient information throughout the tool without any omissions, over-explanations, or irrelevant data

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 1.4.2.b. The tool allows the users to move across different platforms **to allow portability of the tool while retaining their data** (e.g. mobile app vs web app, iOS vs Android, **older smartphones**)

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 1.4.3. The tool can be used in real time (i.e. real-time data tracking), e.g. if the user is experiencing a health issue, reducing waits and sometimes harmful delays for both those who receive and those who give care

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 2.1.1.a. The tool includes high quality interactive features (enables user input and reaction) and is presented in an engaging way (e.g., contains the right mix of video/audio/text/graphics)

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 2.1.1.b. The tool is customisable and allows the user to control all the necessary settings and features (e.g., notifications, alerts, sounds, colours, and fonts) **except for the features that form an essential part of an intervention (e.g. the tool allows the patients to customise the time of a certain reminder according to their daily routine but doesn't allow them to remove it)**

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 2.1.2.a. The tool is persuasive and aims at understanding what influences people's behaviour and decision making, and then uses this information to design compelling user interactions by offering relevant and customisable therapeutic activities and encouraging users to complete them (e.g. through incentivisation, gamification etc.) **in a way that balances engagement vs tool addiction**

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 2.3.1. The tool's visible **and verified** users' reviews and ratings are favourable (e.g. a star rating above 4/5 stars **in the app store, or the Net Promoter Score - NPS**). Using users' perceived value through users' reviews and ratings as a proxy for quality, usefulness, or acceptability and popularity

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 2.4.1.a. The tool has been verified, given a good review, or endorsed by a legitimate/reliable source such as a health organisation or health authority (e.g. APA; FDA in the US; NIH; NHS in the UK; NICE in the UK) **or recommended by trusted Healthcare Professionals**

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 2.4.1.b. The tool provides possibilities for peer support and/or social networking (**e.g. anecdotal evidence - a space to share experiences like patient forums, groups etc.) and/or supported by patient organisations or advisory groups**

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 3.1.3. The tool is implemented and utilised within the target health system under usual care OR a large group of clinicians officially refers patients to utilise it (this can be checked by looking at the unique monthly users and their percentage in relation to the target population in the target health system/market). **The size of the target population needs to be evidence based**

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 3.2.1. Assesses the extent to which the tool can be implemented as intended (i.e., feasibility of implementing the tool at a pre-determined date and time). This can be checked by looking at how long it takes, on average, from the contractual agreement until the tool is fully up and running in a healthcare organisation

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 3.3.1. How favourable are the pre-conditions (strategic, political, and environmental contexts) that influence the scaling up of the eHealth tool. For example, the tool's suitability to the socioeconomic context in question, considerations of foreign languages that the tool needs to support, literacy level, and the local regulatory environment **such as reimbursement**

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 3.4.1.a. Contact details of the tool's provider are available, easy to find, and include office address, email, and team members details

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 3.4.1.b. Availability of information and credentials of the individuals and organisations involved in the development and funding of the tool (transparency on the involvement of any parties that may lead to conflict of interest, e.g. commercial sponsors and partners, financial disclosure)

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

* 3.4.4. The tool's provider **and/or its core team members** have specific experience in the eHealth field OR academic institution (e.g., university) OR health care system (or large health providers' organisation). **E.g. an experienced medical director that oversees the algorithms / contents / features of the tool**

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
★	★	★	★	★	○

Please let us know if you have any comments (kindly note that no new criteria will be added at this stage as there won't be a chance to validate them with the expert panel)

Assessment of the additional criteria suggested by the experts in Round 1

* 1.3.1.d. The content has been reviewed by patients to ensure readability and acceptability

1 I suggest this criterion is excluded

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5 This criterion is extremely relevant

I can't assess

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* 1.3.1.d. The risk categories that are valid for this criterion (select from the dropdown menu)

* 1.4.1.d. The tool explicitly and easily enables users to delete their data

1 I suggest this criterion is excluded

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5 This criterion is extremely relevant

I can't assess

★

★

★

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* 1.4.1.d. The risk categories that are valid for this criterion (select from the dropdown menu)

* 1.4.3.b. The tool is reliable and available at all times and can handle high levels of traffic and usage, with backup and recovery measures in case of downtime or system failures (e.g. enabling offline functionality, functioning during energy interruption or under difficult environmental conditions)

1 I suggest this criterion is excluded

2

3

4

5 This criterion is extremely relevant

I can't assess

★

★

★

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* 1.4.3.b. The risk categories that are valid for this criterion (select from the dropdown menu)

* 1.4.4. The tool compliantly allows for data sharing and segregation for research use (including data analytics and reporting, quality improvement initiatives, and clinical trials)

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
					<input data-bbox="1209 357 1242 399" type="radio"/>

* 1.4.4. The risk categories that are valid for this criterion (select from the dropdown menu)

* 1.4.5. Data findability and retrievability: Metadata definition (including e.g. units used, reference to controlled vocabularies, ontologies) and the ability for users to retrieve data with the same granularity specified by the metadata (up to and including raw data sets)

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
					<input data-bbox="1209 924 1242 966" type="radio"/>

* 1.4.5. The risk categories that are valid for this criterion (select from the dropdown menu)

* 1.5.1.c. The tool is usable and accessible in the intended clinical setting (e.g. if it is used by HCPs in a clinical setting, can they use it while wearing gloves, e.g. are buttons big enough and separated)

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
					<input data-bbox="1209 1428 1242 1470" type="radio"/>

* 1.5.1.c. The risk categories that are valid for this criterion (select from the dropdown menu)

* 2.1.3.c. Affordability of the tool taking into account the local socioeconomic context, and clarity on who pays and how do they pay

1 I suggest this criterion is excluded	2	3	4	5 This criterion is extremely relevant	I can't assess
					<input data-bbox="1209 1890 1242 1932" type="radio"/>

* 2.1.3.c. The risk categories that are valid for this criterion (select from the dropdown menu)

* 2.2.3.d. The tool differentiates between clinical and technical feedback, and clearly channels clinical feedback that may pose a health risk through the proper channels (e.g. advising the patient to call their care team, go to the ER...) and reviews them for vigilance and post-market surveillance purposes and, where relevant, notify them to competent authorities

1 I suggest this
criterion is
excluded

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5 This criterion is
extremely
relevant

I can't assess



* 2.2.3.d. The risk categories that are valid for this criterion (select from the dropdown menu)

* 3.4.5. Availability of phase-out scenarios, if the tool's provider stops producing/maintaining the tool

1 I suggest this
criterion is
excluded

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5 This criterion is
extremely
relevant

I can't assess



* 3.4.5. The risk categories that are valid for this criterion (select from the dropdown menu)

Please let us know if you have any comments (kindly note that no new criteria will be added at this stage as there won't be a chance to validate them with the expert panel)

Thank you for your valuable time and contribution. You will hear from the research team as soon as the final results have been peer reviewed to ask for your consent (or not) to be publicly recognised as a contributing expert in the planned white paper.