Assessing the quality & impact of eHealth tools

A Practical Toolbox

An Interactive Playbook

Innovation project supported by

Schweizerische Eidgenossenschaft
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An Interactive Playbook

eHealth Assessment Toolbox

This is an interactive document, clicking on the different elements in the structure takes you directly to the respective section.

This also applies to the left and right hand navigation elements.

Clicking on the “home” icon always takes you back to this overview.

Version 1: February 2024.

Read more: **https://ehealth-criteria-toolbox.net/**

About

This section summarises the project background, research team, practice and development partners, and funding.

About this project

The current era of technological progress has given rise to a multitude of eHealth tools, numbering in the hundreds of thousands, accessible to users. Despite this abundance, only a handful undergo expert evaluation, with the majority faltering during the pilot phase due to an inability to demonstrate value.

Numerous assessment initiatives and frameworks exist, but they grapple with significant challenges. These hurdles include the contextual intricacies of healthcare, insufficient validation, incompleteness of criteria, and impracticality. Recognizing these obstacles, we initiated this project with the aim of addressing some of these pressing issues.

Our project was initiated to shift from theoretical endeavors to the provision of a practical eHealth assessment toolbox. This resource is designed for active use by stakeholders in their daily decision making. By incorporating insights from past initiatives and leveraging a co-creation approach with practice partners and industry experts, our goal is to address identified gaps and challenges.

Crafted in a practice-oriented style, our eHealth assessment toolbox caters to the everyday needs of stakeholders. It takes into consideration the social, organizational, and technical aspects of healthcare technology assessment, adoption, and implementation.

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Project Lead

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University of Applied Sciences and Arts

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This project is jointly **sponsored by** F. Hoffmann-La Roche Ltd., KPT insurance, and Innosuisse (the Swiss Innovation Agency, grant 104.445 IP-ICT).

Jacob et al. **Assessing the Quality and Impact of eHealth Tools: Systematic Literature Review and Narrative Synthesis**. JMIR Hum Factors 2023;10:e45143 doi: 10.2196/45143

Jacob et al. **A sociotechnical framework to assess patient-facing eHealth tools: results of a modified Delphi process**. npj Digit. Med. 6, 232 (2023). https://doi.org/10.1038/s41746-023-00982-w

"This project is a beacon of commitment to excellence in healthcare as the trend of digitization in medicine gears towards more personalized care, it allows stakeholders to choose the highest quality medical tools with confidence, and accelerates the development of tools that uphold the highest utility"

Katharina Mahadeva Cadwell, MD
Medical Doctor

"Patient-Facing eHealth Tools are key to better healthcare. Open frameworks to assist their development by solution providers and their assessment by payers and patient advocacy groups are a must. Jacob et al. provide an important step in this direction"

Giovanni Nisato, PhD
Digital Health Expert

"This is an important and timely project to help direct both digital healthcare developers and health care providers develop solutions that meet the needs of people with health conditions in a safe but pragmatic way"

Richelle Flanagan
Patient Advocate and Expert

Disclaimer

The toolbox and all its components are 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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Objectives

This section summarises the project aims and potential uses of its outcomes.

Why is this project relevant?

Among the myriad eHealth tools available, the majority face hurdles during pilot phases, either due to an inability to demonstrate value or encountering implementation barriers [1,2]. A scant few have undergone systematic assessment or evaluation [3–5]. Additionally, prior studies appraising existing eHealth tools have revealed significant shortcomings, including the omission of crucial features necessary for achieving intended objectives, notable technical deficiencies, or only modest clinical utility [6–8].

This complex landscape poses a formidable challenge for stakeholders such as patients, healthcare providers, payers, and industry entities like pharmaceutical companies. Identifying high-quality eHealth tools amid this abundance is particularly daunting [6,9], exacerbated by the absence of standardized assessment approaches [6,9,10].

Despite the development of numerous assessment frameworks over the past decade, the lack of standardization in this domain presents a significant challenge [4,11,12].

A comprehensive initial systematic review of this area [11] revealed that many existing assessment frameworks lack validation with relevant stakeholders [6,13,14]. This limitation can lead to assessment processes that may not adequately address the real-world needs of diverse populations [6]. Often, these frameworks remain at a conceptual level, offering limited practical guidance for integration into routine decision-making [12,14–16].

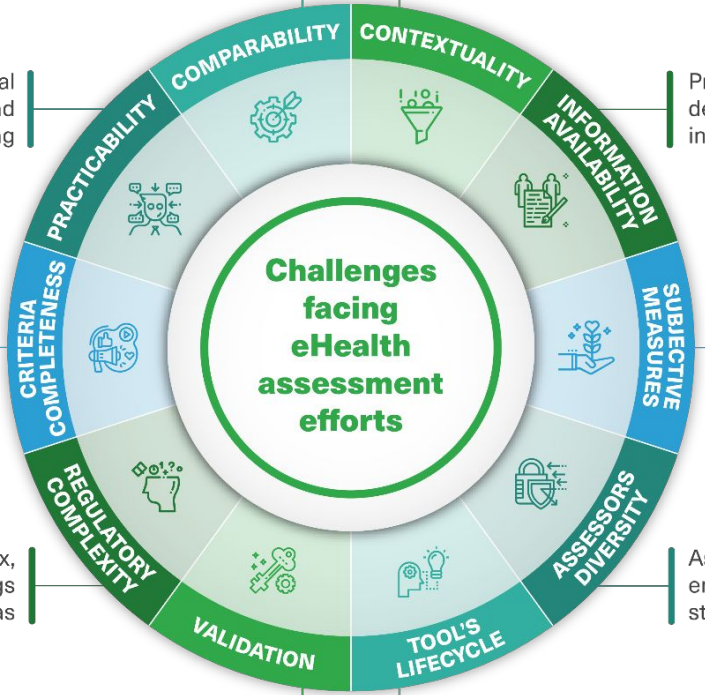
Moreover, certain frameworks neglect essential assessment criteria, resulting in incomplete or issue-specific evaluation frameworks [17–21]. This underscores the need for more robust and comprehensive approaches to eHealth assessment.

Similarly, the European regulatory system provides the Conformité Européenne (CE) mark, which indicates compliance with European legislation. However, it is important to note that this mark primarily verifies safety and performance, not necessarily clinical efficacy [26].

A recent examination of user reviews for DiGA-certified apps in Germany (Digitale Gesundheitsanwendungen, denoting digital health applications prescribed with costs covered by standard statutory health insurance) revealed user dissatisfaction with the perceived limited value of these tools. This suggests that the certification process and the emphasis on clinical evidence might not consistently translate into perceived value among users [27].

These regulatory gaps underscore the notion that the safety, efficacy, and ethical compliance of certified eHealth tools may not always be guaranteed [28].

Challenges facing eHealth assessment efforts



The multitude of assessment frameworks and the heterogenous methodologies used are barriers to comparability and standardization

e-Health interventions are highly contextual, making it crucial to take the implementation context and use cases into account

Many of the existing initiatives are conceptual without granular guidance on how to use and apply them in day-to-day decision making

Proper assessment is mostly dependent on developer transparency and availability of information, which is not always the case

Some existing frameworks are criticized for overlooking important assessment criteria

While most assessment criteria are objective, some of the criteria that are most relevant for user engagement are subjective (e.g. ease of use)

The regulatory landscape is complex, scattered, and not free of shortcomings and grey areas

Assessor profiles are not always diverse enough to reflect the views of all relevant stakeholders

The validity and reliability of existing tools has not always been rigorously tested and validated

Most frameworks focus on tools that are fully operational, not those that are still under development

Initially published in: Jacob et al. Assessing the Quality and Impact of eHealth Tools: Systematic Literature Review and Narrative Synthesis. JMIR Hum Factors 2023;10:e45143. doi: 10.2196/45143

Scope & Objectives

Addressing the prominent challenges of validation and assessor diversity in eHealth assessment endeavors, a primary objective of this project was to corroborate the findings from our systematic review. This validation process involved engaging a diverse expert panel through a modified Delphi process. The aim was to rigorously examine the initial criteria list, subjecting it to scrutiny from experts representing all relevant stakeholders.

Through this collaborative effort, the goal was to discern which criteria were indispensable, classifying them as "must-have," while identifying others that were less critical and could be categorized as "nice-to-have." Additionally, the process sought to uncover any criteria that may have been overlooked initially and should be incorporated into the validated framework. Addressing the challenge of contextuality, we deliberately included contextual criteria in the initial list, seeking expert input to validate their relevance.

Our objective was to tackle the challenge posed by the impracticality of certain past initiatives. To achieve this, we went beyond merely validating and supplementing the criteria list. Instead, we extended our engagement with experts, fostering a broader dialogue to explore ways of enhancing the usability and accessibility of the proposed assessment instrument. The intention was to provide robust support for decision-makers in their day-to-day decision-making processes.

While some existing assessment initiatives concentrate on curating, certifying, or accrediting eHealth tools to aid customers in distinguishing between low- and high-quality options [9], our focus differs. **This work aims to empower decision-makers** with an assessment instrument tailored to support their decision-making based on their specific needs and priorities within the distinct contexts where they are evaluating a tool.

Educational purpose

The toolbox and all its components are intended for educational purposes only and is not intended as legal advice.

Patient-facing tools

This work focuses on patient-facing eHealth tools, including self-management tools and remote eHealth solutions, rather than tools used within and between care providers (e.g., HCP video-conferences, or EHR integration), or health data analytics systems used at population level.

Who can benefit from this assessment instrument?

The insights gleaned from this work will provide valuable guidance to a diverse range of stakeholders, including clinicians, pharmaceutical executives, insurance professionals, investors, technology providers, and policymakers.

The project presents a validated sociotechnical framework that comprehensively considers various criteria for assessing patient-facing eHealth tools. Importantly, the framework not only evaluates these tools from a technological standpoint but also takes into account their contextual relevance. This comprehensive perspective equips stakeholders to make well-informed decisions regarding which tools to utilize, endorse to patients, invest in, collaborate with, or reimburse. Such decisions can be based on the potential quality of the tools and their suitability within the specific context for which they are being evaluated.

Clinics and Hospitals

The management teams in clinics and hospitals may use the assessment criteria when deciding which tools to license; clinicians may also benefit from it when deciding which tool to endorse to their patients.

Pharma Companies

Players in the Pharma industry may benefit from the assessment criteria when assessing and comparing eHealth tools they are considering to partner with, invest in, or acquire.

Insurance and Investors

Payers and insurance companies and investors may use the criteria when deciding which tools to partner with, invest in, or reimburse.

Technology Providers

Technology providers in the digital health space may benefit by ensuring that their tools meet all the key quality criteria to facilitate user acceptance and adoption.

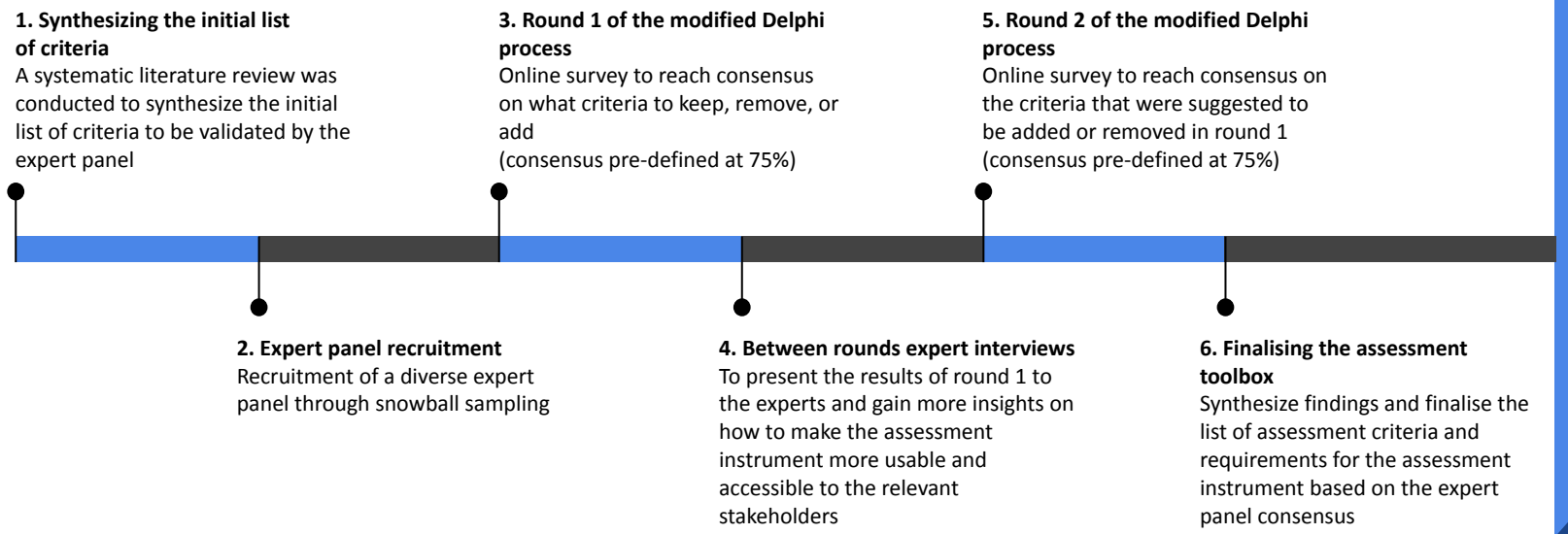
Methods

This section summarises the methodology we followed to achieve the results presented in this document.

How we achieved the results that we are presenting here

This project extends from a foundation of rigorous scientific research and embraces a co-creation approach involving practice partners and industry experts. The primary objective is to develop a practical eHealth Assessment Toolbox explicitly crafted for daily use. The resulting toolbox is constructed within a comprehensive framework that thoroughly incorporates the social, organizational, and technical criteria integral to healthcare technology assessment.

The collaborative nature of this endeavor ensures that the resulting assessment instrument and educational material are not only informed by scientific rigor but are also highly relevant and applicable to the everyday practices of our partners and experts in the field.



Foundational work

We wanted to build on the growing body of research that investigates the criteria used to assess the quality and impact of eHealth tools.

Our research commenced with a systematic literature review aimed at comprehending the diverse approaches and criteria employed in evaluating the quality and impact of eHealth tools. We conducted searches on prominent databases, including PubMed, Cochrane, Web of Science, Scopus, and ProQuest, focusing on studies published in English between January 2012 and January 2022. The initial search yielded 675 results, from which 40 studies meeting our inclusion criteria were identified. To maintain a systematic process, we adhered to the PRISMA guidelines and followed the Cochrane Handbook for Systematic Reviews of Interventions.

By aggregating similar measures from various papers, frameworks, and initiatives, distilled into unique criteria organized into clusters. Employing a sociotechnical approach, we classified these criteria into technical, social, and organizational assessment categories. This categorization allowed for a holistic understanding of the multifaceted aspects influencing the assessment of eHealth tools.

A peer-reviewed paper that transparently reports on the method and outcomes of the systematic literature review has been published in JMIR Human Factors and can be accessed here:

humanfactors.jmir.org/2023/1/e45143

Delphi study

To address some of the challenges identified in our foundational work, we aimed to validate the initial list of assessment criteria derived from our systematic review through an expert panel with diverse perspectives. Expert consensus was instrumental in categorizing criteria into must-have and less critical ones, and in identifying any missing criteria for inclusion in the validated framework. Moreover, our discussions with experts extended beyond the final list of criteria, delving into their diverse perspectives on optimizing the accessibility and usability of the assessment instrument.

This validation process involved a two-round modified Delphi method, with interspersed rounds of interviews, to refine the initial list of 55 assessment criteria synthesized from our systematic literature review of existing frameworks. Consensus, pre-defined as at least 75% agreement among experts, guided the process. Two rounds of electronic voting were conducted. Preceding Round 2, one-to-one semi-structured interviews were conducted to explore the perspectives of diverse stakeholders on key challenges and directional decisions related to the proposed assessment instrument.

A peer-reviewed paper that transparently reports on the method and outcomes of the Delphi study has been published in npj Digital Medicine and can be accessed here:

www.nature.com/articles/s41746-023-00982-w

Expert Panel *(1 of 3)*

The 57 experts that contributed to the Delphi study were instrumental in shaping this work. The international panel included experts from **9 stakeholder groups and 18 countries**. Several participants had multiple roles and backgrounds or were active in more than one geography; hence, there was an overlap in some of these sample characteristics.

Stakeholder groups represented in this panel are: clinicians, patients and patient advocates, researchers, pharmaceutical executives, insurance and reimbursement experts, compliance experts, investors and funding experts, and medical technology providers.

The 54 experts recognised here are the experts who agreed to be acknowledged and are shown in alphabetical order. Experts who did not explicitly waive their anonymity are not named here.

Click on the photos to access their LinkedIn.


Aahuti Rai
Strategic Advisor & Venture Partner in Health Innovation


Aamani Budhota, PhD
Digital Health Innovator


Alexander Klein
Digital Health Expert


Amine Korchi, MD
Radiologist and Digital Health Expert


Aurelie Moser
Digital Health Innovation Management Expert


Brian Li Han Wong
Digital Health Expert


Cécile Tardy-Srinivasan
Digital Health Expert and EUPATI Fellow


Christiane Grünloh, PhD
Human-Computer Interaction Researcher


Cornelia Trümpy
Health Tech Expert


Danielle Ralic
Digital Health Provider


Danielle Siarri
MSN, RN, NI-BC
Clinical Publisher & Nurse Informatics Specialist


Danina Kapetanovic
CIO & Head of OROT-Connected Health Innovation Hub


Don Grant, CCPE
Patient Partner


Emre Sezgin, Prof, PhD
Digital Health Expert

The experts recognised here are the experts who agreed to be acknowledged (in alphabetical order) - experts who did not waive their anonymity are not named here.

Expert Panel *(2 of 3)*


Fabrice Denis, Prof, MD, PhD, President of the Institute for Smarthealth INeS


Florian Koerber, Prof, PhD
Digital Health Expert


Giovanni Nisato, PhD
Digital Health Expert


Gregg Fisher
Digital Health Expert


Hamza Moftah
Digital Health Expert


Hannes Hudalla, MD
Med Tech Founder


Henri Viertolahti
Digital Health & AI Entrepreneur


Hicham Naim, PharmD
Pharma Executive


Howard Rosen
Digital Health & Patient Engagement Expert


JB (John Bosco) Bunyi, PhD, Technology & Mental Health Researcher


Joachim Stengel
Senior Manager, Digital Health Consultant


Johannes Boshkow
Business Development Director, Dawn Health


Julia Muellner, MD
Deputy Head of eHealth Switzerland


Katharina Mahadeva Cadwell, MD
Medical Doctor


Maren Schinz, PhD
Digital Health Expert & Patient Expert


Mariam Shokralla, PharmB, MSc, MPH
Digital Health Strategist


Marko Kuisma
Investor & Digital Health Expert


Mayella Favre
Market Access & Reimbursement Expert


Mike Braham
Patient Partner


Mohanad Fors, PharmD
Digital Health Expert

The experts recognised here are the experts who agreed to be acknowledged (in alphabetical order) - experts who did not waive their anonymity are not named here.

Expert Panel *(3 of 3)*

Pascal Clisson, MBA
Patient Advocate & Expert

Patrick Kaltenrieder, PhD
Head of Digitalization

Petronela Sandulache, MA, CEMS, Digital Health Entrepreneur

Raouf Hajji, MD, PhD, Digital Health Expert, Medicine Faculty of Sousse

Renaldo Bernard, PhD
Digital Health Strategist

Richelle Flanagan
Patient Advocate & Expert

Roland Bosshard
CIO & Member of the Management Board

Samantha Connolly, PhD
Digital Health Expert

Samantha Mourrain, MS, BSN, RN, Patient Advocate & Expert

Samer Tadross, Founder & CEO, MedTech provider

Samuel Ohayon
Health Tech Expert

Sara Ahmed, Prof, PT, PhD
Digital Health Expert

Smit Patel, PharmD
Digital Health Strategist

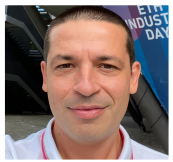
Steve Bourke
Consultant Patient Advocate

Sunjoy Mathieu
Digital Health Expert

Tazeen Rizvi, MD
Digital Health Expert

Thomas Sauter, Prof, MME, MD
Professor of Emergency Telemedicine

Thomas Metcalfe, Cluster lead PHC Ecosystem, Personalized Healthcare Center



Ventsislav Dobrev, PharmD, MBA
Digital Health Advisor

Vladimir Murovec, Digital Health Regulatory Counsel

The experts recognised here are the experts who agreed to be acknowledged (in alphabetical order) - experts who did not waive their anonymity are not named here.

Criteria

This section summarises the criteria resulting from the Delphi study and strategic considerations for the assessment instrument.

Tackling the challenges

We systematically considered the significant challenges inherent in eHealth assessment efforts, as outlined in our foundational work. While acknowledging that certain challenges, such as information availability and regulatory complexity, were beyond our direct control, we directed our efforts towards addressing key issues within our purview.

Specifically, our focus encompassed validating assessment criteria with intended users and stakeholders to align with real-life needs, ensuring diverse perspectives by including a varied expert panel, accounting for healthcare contextuality, exploring strategies to tackle subjective measures, and enhancing the practicability of the proposed assessment instrument to maximize accessibility and usability.

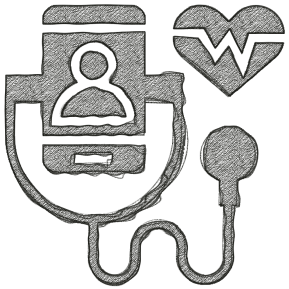
The expert panel played a crucial role in validating the assessment criteria, leveraging the diversity of participants to incorporate various priorities and perspectives from relevant stakeholders.

The initial set of criteria included contextual elements that experts confirmed as must-haves in the final framework. Furthermore, experts were invited to propose additional assessment criteria they deemed significant. These new criteria underwent validation in a second-round survey to ensure the comprehensive inclusion of all relevant factors in the final list.

Our interviews with the experts extended beyond the finalization of assessment criteria, encompassing discussions on the practicality and relevance of the proposed assessment instrument. The aim was to enhance its accessibility and usability for decision-makers in a manner that aligns with their needs.

"This sociotechnical framework and its thoughtfully selected clustering empower outcome-driven HealthTech adoption. Seamless transitions between analog and digital realms are crucial in contemporary health management, emphasizing communication, participation, and transparency for all prospective (e)patients"

Cornelia Trümpy
Health Tech Expert



Why a sociotechnical assessment framework for eHealth?

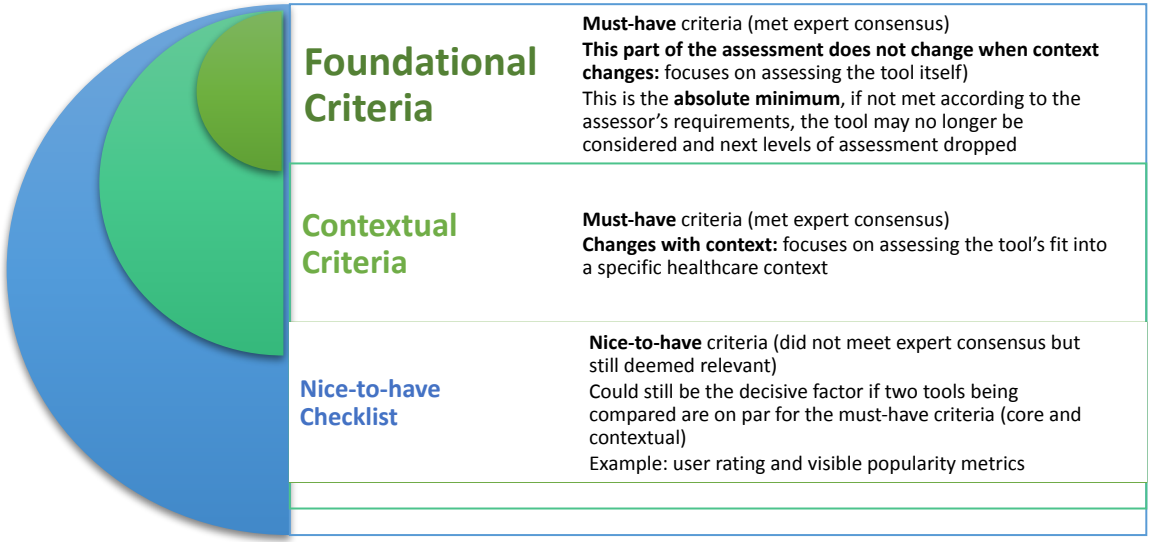
The categorization of clusters into foundational and contextual criteria serves a dual purpose: addressing the assessment of the tool's quality independent of its context and evaluating the potential impact of the tool within a specific setting, considering its contextual fit. This approach, rooted in the concept that understanding and enhancing the design and performance of any innovation requires integrating both 'social' and 'technical' aspects as interdependent components of a complex system [29], goes beyond evaluating isolated technologies. Instead, it considers the intended context, acknowledging the interconnected nature of social and technical elements.

Simultaneously, the categorization of criteria into foundational and contextual elements enhances the efficiency of the evaluation process for assessors tasked with appraising a tool across multiple potential contexts. This approach minimizes redundancy, as assessors only need to repeat the contextual assessment for each new scenario, while the evaluation of foundational criteria remains consistent throughout.

This streamlining of the process ensures a more effective and streamlined assessment, particularly when considering the applicability of the tool in diverse contexts.

It's important to acknowledge, however, that the rapid pace of technological advancements necessitates periodic revisions of the assessment to accurately evaluate how the tool evolves with technological progress.

The incorporation of the supplementary nice-to-have checklist stemmed from the observation that all criteria in this cluster, with the exception of two, achieved a consensus level exceeding 50%. Thus, the inclusion of these additional criteria may hold value in certain instances, even if they do not qualify as must-have requirements.



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Foundational criteria

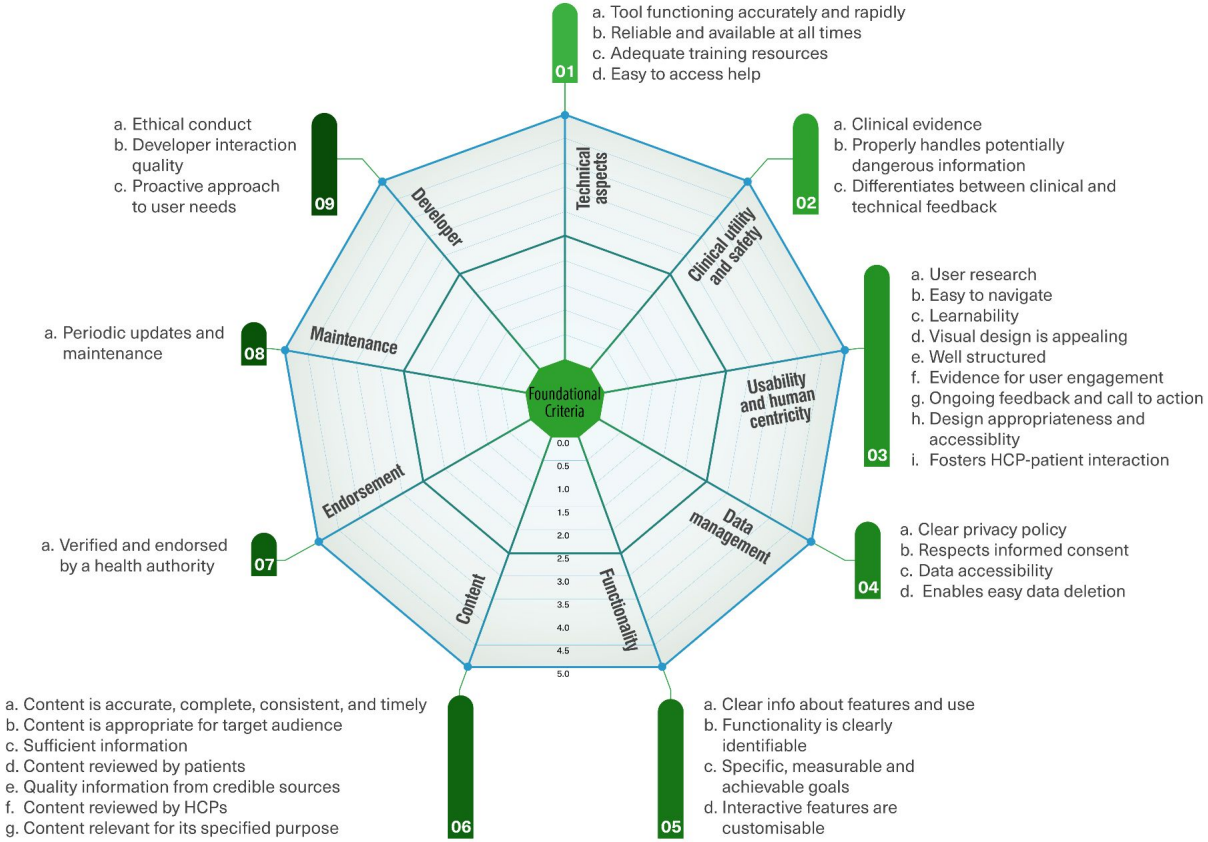
The focus of this part of the assessment is to address the question:

"***what is the assessment of the quality of the tool itself regardless of its context?***"

The foundational criteria encompass nine clusters: technical aspects, clinical utility and safety, usability and human centricity, functionality, content, data management, endorsement, maintenance, and the developer.

Some of these clusters include more than one subcriterion.

Scale definition: criterion is fully met (5/5), partially met (2.5/5), or not met (0/5).



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Foundational criteria definitions *(1 of 2)*

01. **Technical aspects**

Assesses whether the tool is functioning accurately and rapidly, is reliable and available at all times and can handle high levels of traffic and usage, provides adequate and user-friendly training resources for end users, and it is easy and obvious to access technical help when needed.

02. **Clinical utility and safety**

Assesses whether the tool's clinical effectiveness is supported by strong research with adequate statistical power conducted by credible sources, warns about potential risks when necessary and properly handles potentially “dangerous” information entered by a patient, and differentiates between clinical and technical feedback, and clearly channels clinical feedback that may pose a health risk through the proper channels.

03. **Usability and human centricity**

Assesses whether the tool's usability and acceptability has been rigorously trialed and tested in a real world setting, learning to use the tool is easy and does not require a lot of time, the visual design is appealing and has a harmonious look and feel, is well structured, and important information is clear and stands out, there's evidence for co-creation and collaboration with users in the tool's development, provides appropriate ongoing feedback and appropriate call to action based on the user’s state and activities (when applicable), its content and design are appropriate for the target audience and accessible to vulnerable populations, and has the ability to foster the interaction between the health care professionals and their patients (when applicable).

04. **Data Management**

Assesses whether the tool has a clear privacy policy and informs the users on how their data will be kept confidential and secured and how the data may be used, respects informed consent and allows the user to opt out of data collection, its data can be accessed at any time and on different platforms and operating systems, and it explicitly and easily enables users to delete their data.

05. **Functionality**

Assesses whether there is clear information about the tool's features and appropriate ways to utilize it, the functionality of each element is clearly identifiable, the tool has specific, measurable and achievable goals (desired outcomes) that are specified/obvious within the tool itself, and interactive features such as reminders, push notifications, and prompts are customizable and not overwhelming.

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Foundational criteria definitions *(2 of 2)*

06. **Content**

Assesses whether health-related content is accurate, complete, consistent, and timely; is provided in a clear and appropriate way for the target audience; there is sufficient information throughout the tool without any omissions, over-explanations, or irrelevant data; the content has been reviewed by patients to ensure readability and acceptability; the tool contains high quality information from credible and legitimate sources; has been reviewed by (or originated from) healthcare professionals with the most updated evidence-based practice of medicine, and contents are relevant to the underlying objective and likely to be effective in achieving the specified purpose in the specific intended population.

07. **Endorsement**

Assesses whether the tool has been verified, given a good review, or endorsed by a legitimate/reliable source such as a health organization, health authority, scientific/medical society (e.g., APA; FDA in the US; NIH; NHS in the UK; NICE in the UK) or recommended by trusted Healthcare Professionals.

08. **Maintenance**

Assesses whether the tool gets periodic updates and maintenance both from technical and content perspectives (e.g., last update not older than xx months depending on the use case, the content is periodically updated with the new findings in the medical field).

09. **Developer**

Assesses whether the tool's provider respects ethical conduct, clinical responsibility, and the rules and regulations protecting patient's rights and societal interests; interaction quality between the tool's provider and the users, including responsiveness, after sales services, and customer orientation is high; and the tool's provider demonstrates a proactive approach to the assessment of user needs, and continuous learning.

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Contextual criteria

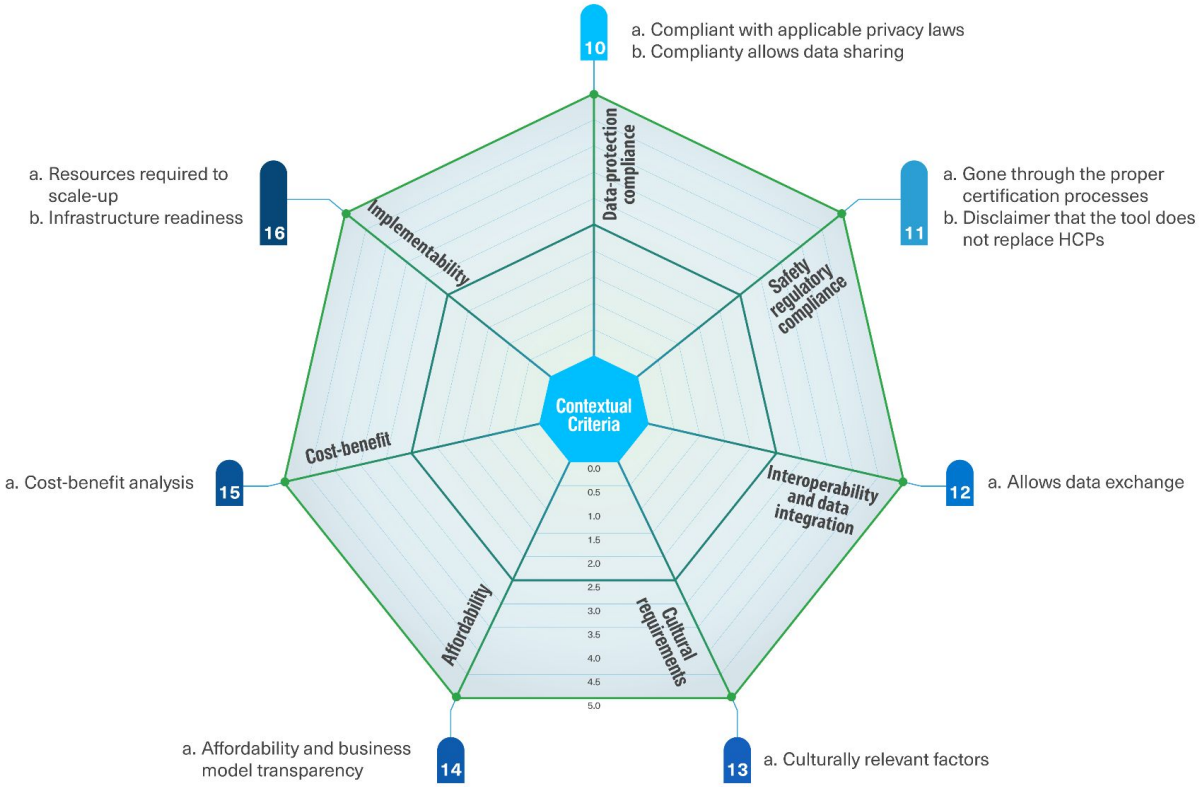
The focus of this part of the assessment is to address the question:

"what is the assessment of the potential impact of the tool in a specific setting given its contextual fit?"

The contextual criteria encompass seven clusters: data-protection compliance, safety regulatory compliance, interoperability and data integration, cultural requirements, affordability, cost-benefit, and implementability.

Some of these clusters include more than one subcriterion.

Scale definition: criterion is fully met (5/5), partially met (2.5/5), or not met (0/5).



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Contextual criteria definitions

10. Data-protection compliance

Assesses whether the tool explicitly reports being compliant with the relevant data privacy and protection laws (e.g., GDPR, HIPAA...), and the treatment of any personal data is compatible with the Patient Data Act, Personal Data Act, and other applicable privacy laws, and compliantly allows for data sharing and segregation for research use.

11. Safety regulatory compliance

Assesses whether the tool's provider clearly identifies the risks that its management may pose for user safety and has gone through the proper certification processes to ensure its safety; and the tool contains a disclaimer that the information provided/content does not replace a health care professional's judgment (when applicable).

12. Interoperability and data integration

Assesses whether the tool allows for interoperability, data integration and exchange of data with other apps, e-tools, wearable devices, electronic health records (ability to exchange data with other systems on a technical and policy level, and with other users such as clinicians or caregivers).

13. Cultural requirements

Assesses whether the tool takes into account culturally relevant factors (e.g., different languages and alphabets, specific religious or cultural requirements or restrictions, gender considerations).

14. Affordability

Assesses whether the tool is affordable taking into account the local socioeconomic context, and whether it is clear who pays for it and how they pay.

15. Cost-benefit

Assesses whether a cost-benefit analysis was performed and led to positive results. I.e., the balance between the costs and benefits arising from the tool's utilization. This refers to the tool's direct costs (purchase price, subscription, licensing…), but may also include costs associated with the tool's selection, staff training, setting up support mechanisms, and appropriate governance.

16. Implementability

Assesses whether the tool fits well into existing workflows and does not require additional resources (workforce, hardware, software) to scale-up and to enable it to function properly; and whether it fits well into the existing infrastructure and does not require investment in additional infrastructure to enable it to function properly (This refers to physical infrastructure such as electricity, access to power, connectivity etc. in the local context).

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The proposed assessment instrument

Given the considerable diversity in eHealth tools, encompassing variations in use cases, integration levels, and safety risk levels, it is crucial to recognize that certain assessment criteria may not universally apply to all tools. Existing studies highlight the difficulty in classifying tools based on current categorizations, primarily due to the lack of standardization in this domain [30]. In our approach, we prioritized safety risk categorization in alignment with the NICE evidence standards framework [14]. This focus on safety aligns with the paramount importance of evaluating tools within the context of potential risks, reflecting a key priority in the assessment process.

The interactive assessment instrument will be accessible on the project website.

Each criterion within the tool is accompanied by a comprehensive description and examples, facilitating assessors in determining whether the criterion is fully met (5/5), partially met (2.5/5), or not met (0/5).

Some criteria offer binary assessment options, with assessors required to determine whether the criterion is either met or not met. For instance, the assessment of whether a tool has undergone proper certification processes is inherently binary and cannot be partially met.

To accommodate scenarios where certain criteria may be optional for some tools, we have introduced the option of (not applicable). For instance, the criterion evaluating whether a tool facilitates interaction between healthcare professionals and their patients may not be relevant for autonomous tools designed for independent use.

In cases where a criterion cluster comprises multiple sub-criteria, the mean score is calculated to represent the average assessment of the entire cluster. We opt for mean scores in line with the common format of star ratings and similar assessment scales [31]. This approach is more suitable than total scores, especially since some criteria may be deemed not applicable in specific cases.

When relevant, assessors are given additional resources to support their evaluation by providing more details about quality standards for this specific criterion. For instance, clinical evidence is one of the criteria in the foundational cluster (clinical utility and safety), which may require deeper examination by employing additional standards tailored for that specific area. In this example, the guidance includes more details on the checklist of the evidence quality criteria of the evidence DEFINED (Digital Health for EFfectiveness of INterventions with Evaluative Depth) framework [32].

Such additional resources aim to help the assessor gain more insights into how to assess the quality of the criterion, particularly in cases where they may not have enough experience in this specific domain.

The following pages present some of the directional decisions that we discussed with the experts.

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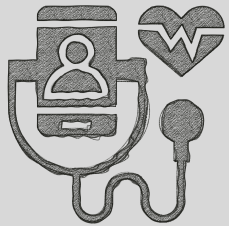
Studies indicate that factors extending beyond the eHealth tool itself, including implementation costs, clinical workflows, necessary resources and infrastructure, as well as a patient's characteristics and socioeconomic status, significantly influence the acceptance and adoption of eHealth [33–38]. The intrinsic contextual nature of healthcare renders engagement with eHealth tools notably challenging when lacking contextual awareness [39]. Despite existing standards for assessing usability and scientific evidence of tools, there appears to be a gap in guidelines supporting the evaluation of their implementation and processes [1]. Consequently, this leads to a deficiency in contextual assessment criteria.

In contrast to several assessment initiatives and frameworks that concentrate solely on evaluating the tool without considering the healthcare context, our advocacy emphasizes the incorporation of contextual criteria. These include factors such as the readiness of local infrastructure, resources needed for scale-up, cost-benefit analysis, reimbursement standards, and cultural aspects like the use of the local language. Extensive evidence underscores the significant influence of these contextual factors on the adoption and scale-up of such tools [34,36,40]. The unanimous expert consensus (100%) on the inclusion of contextual criteria reaffirms their importance and relevance for a comprehensive assessment.

Contextual Criteria



"Innovation is most effective when there is freedom to explore and experiment and this often means ehealth tools are developed without a specific context in mind. This work is important as it validates not just the quality of the tool, but the varying context in which it is used"

Aahuti Rai
Strategic Advisor & Venture Partner in Health Innovation

"The distinction between foundational and contextual assessment criteria is an important conclusion. It can pave the way for harmonisation on the EU level (on core criteria) before investing resources to assess contextual criteria"

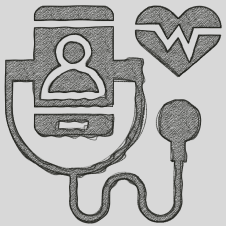
Mariam Shokralla, PharmB, MSc, MPH
Digital Health Strategist

Initially published in : Jacob et al. A sociotechnical framework to assess patient-facing eHealth tools: results of a modified Delphi process. npj Digit. Med. 6, 232 (2023). https://doi.org/10.1038/s41746-023-00982-w

Certain assessment initiatives, which concentrate on curating, certifying, or accrediting eHealth tools, often employ a single-score approach to indicate overall quality. The intention is to facilitate an easy comparison for potential customers, helping them distinguish between low- and high-quality offerings. While these initiatives offer valuable contributions to assessment efforts, scholars contend that they may not offer a sufficiently clear direction on the most effective tools for seamless integration into specific healthcare contexts [6,9]. Consequently, a scorecard approach might be more apt for context-specific evaluations involving multiple stakeholders [6].

The consensus among experts affirmed the preference for a scorecard as a more balanced way to present assessment results, with 78% expressing a preference for this approach. Experts argued that a single score might obscure crucial details, emphasizing that the true value of the assessment instrument lies in understanding the breakdown. This breakdown proves valuable for comprehending the specific strengths and weaknesses of the assessed tool. Some experts (22%) proposed an ideal scenario where assessment results would be presented as a combination of a scorecard and a composite score. This composite score would assign greater weight to assessment criteria deemed a key priority by the assessor for their specific context, enhancing comparability when assessing multiple tools simultaneously.

Scorecard Approach



"The assessment framework was collaboratively devised, with active engagement from key stakeholders within the healthcare system. This framework empowers a comprehensive evaluation of digital health platforms and tools, fostering a profound understanding of their capabilities"

Sunjoy Mathieu
Digital Health Expert

"All too often eHealth tools fail met unmet need, deliver impactful and sustainable outcomes. They are designed and developed in a vacuum not addressing mutual value. The framework is a vital step to change process and mindset towards systematic evaluation"

Steve Bourke
Consultant Patient Advocate

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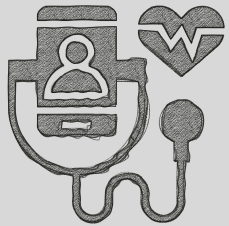
Recent advancements in Artificial Intelligence (AI) have empowered numerous evaluation initiatives to employ sophisticated AI models for appraising eHealth tools. These models scan publicly available information to generate a basic quality assessment swiftly. While this approach allows for the assessment of a large number of tools in a relatively short time, there is a potential risk associated with this mass appraisal method. It may disproportionately favor tools with robust marketing efforts and a polished public image, which may not necessarily translate to superior clinical utility. Another challenge pertains to the scarcity of information [11,41].

Hence, we advocate for a proactive appraisal approach that involves a hands-on trial of the tool and, if necessary, direct communication with the developer. This strategy requires greater engagement and effort from assessors but promises a more comprehensive and in-depth assessment of the tool's quality. Such an approach yields deeper insights into the specific strengths and weaknesses of the evaluated tool, facilitating more informed decision-making. The importance of testing and hands-on trials for a thorough evaluation of eHealth tools has been endorsed by other researchers [9,41].

65% of the experts favored this proactive approach, foreseeing that a proper and in-depth assessment certainly requires hands-on trial of the tool being assessed and getting in touch with the tool developers if needed.

Proactive Appraisal



"The project will have a meaningful impact on patients' access to quality digital health solutions and support their selection of the best suited solutions from the abundance of choice available."

Renaldo Bernard, PhD
Digital Health Strategist

"The researchers worked enormously to obtain not only a globalist vision of eHealth tools assessment by taking into account the insights of all relevant stakeholders but also detailed responses of the eHealth evaluations questions. The results are game-changing and can be excellent references for future eHealth evaluation and studies"

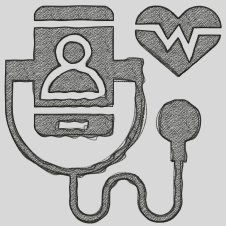
Raouf Hajji, MD, PhD
Digital Health Expert
Medicine Faculty of Sousse

Initially published in : Jacob et al. A sociotechnical framework to assess patient-facing eHealth tools: results of a modified Delphi process. npj Digit. Med. 6, 232 (2023). https://doi.org/10.1038/s41746-023-00982-w

The incorporation of subjective measures has been a topic of debate in the literature due to its potential to introduce variability in assessment outcomes based on the subjective perspectives of assessors. Previous research has demonstrated that certain characteristics of eHealth tools pose challenges for consistent rating [4]. Despite this challenge, several scholars strongly advocate for the inclusion of subjective criteria, including factors like ease of use and visual appeal, given their significant role as fundamental drivers of adoption [34–36,42,43]. Therefore, integrating subjective criteria into the review process holds the potential to enhance tool adherence and improve health outcomes [27]. The consensus among experts unequivocally supports this perspective, with multiple subjective criteria meeting the predefined consensus level.

Experts offered several recommendations to mitigate variability in the assessment of subjective criteria. Foremost among these was advocating for assessor diversity, ensuring a well-rounded assessment that considers various perspectives. To evaluate usability and acceptability, experts suggested leveraging research evidence, such as usability studies. Furthermore, they emphasized the importance of providing clear and specific guidance to assessors, fostering a shared understanding of how to evaluate these subjective criteria and minimizing subjectivity in the assessment process. In instances where rigorous user research is unavailable, using proxy criteria, such as customer ratings, was proposed as a pragmatic approach to gauge a tool's acceptance. It was emphasized, however, that a critical mass of user ratings must be achieved for them to be considered reliable.

Subjective Measures



"eHealth is the future of healthcare and this assessment does important work in evaluating what criteria we should apply to help usher in the right technologies with a successful path that maximizes impact on people's lives"

Danielle Ralic
Digital Health Provider

"The most effective digital innovations are those that are user-friendly. This robust, global study analyzed evaluations of existing appraisal frameworks and through consensus, developed a reliable tool to demonstrate the value of digital-health products"

Don Grant, CCPE
Patient Partner

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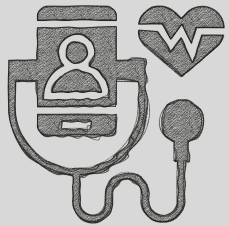
While certain criteria received clear expert consensus, there were ongoing debates in survey comments regarding their applicability to all types of tools. For instance, the criterion evaluating whether the tool facilitates interaction between healthcare professionals and patients achieved an 86% consensus. Nonetheless, some experts contended that this criterion might not be relevant to autonomous tools designed for independent use. As an example, for certain mental health tools, interaction with the traditional healthcare system might not be desired, driven by considerations of anonymity and privacy.

A significant majority of experts (71%) recognized the extensive variability among eHealth tools, underscoring the necessity of allowing for the optionality of certain criteria, despite meeting expert consensus. This aligns with other assessment initiatives and rating systems that similarly incorporate an "not applicable" option for criteria that may be deemed optional for specific tools [41].

Optionality of some Criteria



"There are hundreds of thousands of digital health Apps, making it difficult to select the right app for the right patient. This socio-technical framework takes a holistic approach and provides structure, clarity and confidence during the decision-making process. Its use will allow healthcare professionals, decision-makers and patients to make the best informed decision"

Amine Korchi, MD
Radiologist & Digital Health Expert

"This framework is invaluable to help navigate the maze of factors contributing to designing e-health solutions that make an impact for patients"

Joachim Stengel
Senior Manager
& Digital Health Consultant

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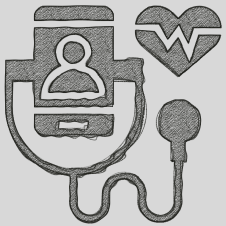
Certain criteria were subjects of disagreement, with some experts perceiving them as shortsighted or potential impediments to innovation. For example, the safety criterion assessing whether the tool includes a disclaimer indicating that the information provided does not replace a healthcare professional's judgment gained an 81% consensus for tools with a higher safety risk (risk tiers B and C). However, three experts advocated for a more progressive assessment framework that would exclude such a criterion, especially in light of the proliferation of AI-driven medicines. This progressive stance may be rooted in the 'fail fast, fail often' ethos prevalent in technology startups, which can clash with the complex regulatory landscape of healthcare. The healthcare sector often follows a more cautious and deliberate process characterized by increased risk aversion guided by the 'first, do no harm' principle [9,44].

The tension between balancing safety and innovation was explicitly recognized by the FDA's Commissioner who acknowledged that eHealth tools are advancing more rapidly than the agency's regulatory capacity [45]. The overwhelming majority of experts (91%) expressed a preference to uphold patient safety. Many experts acknowledged that assessment criteria are intricately tied to the prevailing healthcare context, particularly the progressiveness of regulations and legislation. Consequently, the potential restrictiveness is not inherent to the criteria themselves but is more closely linked to the regulatory landscape and legislation maturity. Accordingly, the assessment framework and the corresponding criteria list are expected to evolve over time to align with changing technologies and regulations.

Current vs. Progressive Criteria



"Unlocking the potential of digital health means holding innovation accountable. Rigorous evidence assessment isn't an option; it's the key to ensuring safe, effective, ethical, and equitable solutions in the tech-driven future of healthcare"

Smit Patel, PharmD
Digital Health Strategist

"The eHealth tools assessment instrument provides pharmaceutical and medtech businesses involved in eHealth with invaluable criteria against which they can evaluate digital health technologies at any pre-launch stage, including prior to development, outsourcing or investment. Naturally, regulations sit among key indicators."

Vladimir Murovec
Digital Health Regulatory Counsel

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Toolbox

This section summarises the components of the eHealth assessment toolbox and where to find them.

A practical toolbox

The proposed framework and assessment instrument require time and expertise.

Therefore, the project team identified the need to create detailed training materials and assessment guidance to support assessors from the different stakeholder groups in their assessment efforts.

The toolbox comprise this document (the playbook), the peer reviewed papers that transparently report on the methodology followed in this project in order to achieve the results used in the assessment framework, and the assessment instrument including the interactive dashboard.

Additionally on-demand webinars and training workshops are offered to interested stakeholders to help raise awareness and upskill the relevant stakeholders in their respective organizations (e.g. Pharma, Insurance, Med Tech).

All resources are available for free access or to be requested on the project website.

The comprehensive and easy to use educational resources available in the eHealth assessment toolbox were created with the aim to support the relevant stakeholders and decision making in the eHealth assessment efforts.

"The toolkit is an amazing resource to bring clarity to a complex jungle of metrics and 'success' stories. The tool should help all players in the field, providers, payers, pharma, and start-ups, define appropriate strategies and selections of evolving technologies"

Johannes Boshkow
Business Development Director, Dawn Health

Where to find the toolbox

All resources and components of the toolbox can be accessed or requested on the project website:
https://ehealth-criteria-toolbox.net/toolbox/

Downloadable resources include the playbook and papers, but also a direct download of the criteria summary for the different clusters, and their respective definitions.

Stakeholders may also request a webinar or a training workshop for their organisation. Such educational opportunities enable direct interaction with a tutor from the research team (University of Applied Science Northwestern Switzerland), question and answers, and hands-on guidance on how to use the assessment instrument.

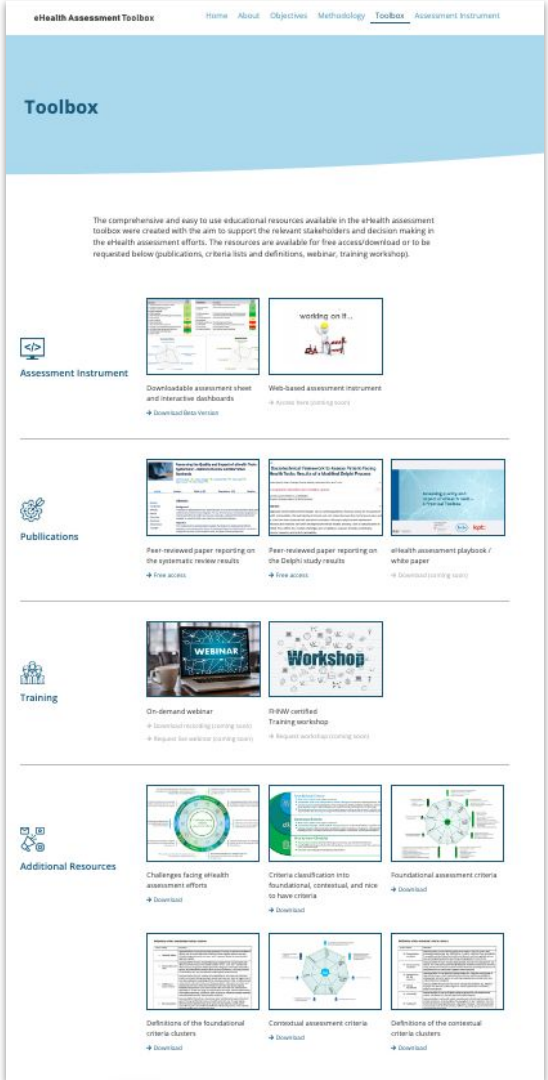
The training sessions may be organized on-site (only for Switzerland), or online. Request forms can be accessed on the project website, on the toolbox page.

The assessment instrument is available in two forms:

A downloadable pre-programmed excel file that can be used locally on the user's computer.

A web based assessment instrument where the assessors can input their assessment of each criterion and download a report comprising the assessment outcomes and dashboards (requires login to enable users to complete the assessment in more than one session and to be able to edit it later).

These resources will be periodically updated to reflect the latest advancements in technologies (should the required funding be secured).



What's next?

Additional research is needed to conduct a pilot test of the proposed assessment instrument, assessing its accessibility and usability among various stakeholders.

Furthermore, exploring its adaptability, such as its potential role as a requirements checklist for developers working on tools in development, is crucial.

Anticipated refinements in the future will involve adjustments to the assessment criteria, their definitions, and the potential inclusion of additional criteria.

This ongoing evolution is deemed necessary, particularly in response to the continuous evolution of new technologies as well as developments in eHealth regulations.

Our goal is also to expand this project, and start building an online database of assessments based on assessors input in the web-based assessment instrument, in order to enable benchmarking and comparability (data will be processed in an aggregated and anonymised form).

Therefore, we need additional funding and partnerships in order to realise these pilot tests, updates, and expansions.

Seeking Partners

We are looking for partners and sponsors to help us take this work to the next level (pharma, insurance, med tech, research partners…)

Get in touch

If you are interested in partnering with us on this endeavor and/or in sponsoring this expansion with financial support, please don't hesitate to reach out to the project lead (Christine Jacob)

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