mHealthHUB European

D2.1 Knowledge Tool 1

Health apps assessment frameworks

ITU

World Health Organization

Junta de Andalucía
Consejería de Salud y Familias

Final Report

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mHealthHUB European
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Statement of originality

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List of abbreviations

AAL	Active Assisted Living
ACSA	Agencia de Calidad Sanitaria de Andalucía (Andalusian Agency for Healthcare Quality)
AFs	Assessment frameworks
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
BSI	British Standards Institution
DiGA	Digital Health Applications (DiGA)
DLA	Danish Lung Association
DMSS	Danish Multiple Sclerosis Society
EC	European Commission
EHR	Electronic Healthcare Record
EMA	European Medicines Agency
EPF	European Patients Forum
EU	European Union
FAQ	Frequently Asked Questions
FPS	Fundación Progreso y Salud (Andalusia)
GDPR	General Data Protection Regulation
GGD	Association of Regional Public Health Services (Netherlands)
GHOR	Regional Medical Emergency Preparedness and Planning (Netherlands)
IT	Information Technology
ITU	International Telecommunication Union
KT	Knowledge Tools
MDR	Medical Devices Regulation
NDA	Norwegian Diabetes Association (NDA)
NIS	EU 2016/1148 Network and Information Security (NIS) Directive
PCHAlliance	Personal Connected Health Alliance
SME	Small and Medium Enterprises
WHO	World Health Organization

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Executive Summary

The **European Innovation and Knowledge mHealth Hub** (https://mhealth-hub.org/) is a project established by the International Telecommunication Union (ITU), in partnership with the World Health Organization (WHO) and the Regional Ministry of Health of Andalusia (Spain) to support the integration of mHealth programmes and services into the national health systems of European countries.

The Hub project is funded by the European Commission under the Horizon 2020 program and is underpinned by a consortium of 17 public and private partners from 12 European countries led by the Andalusian Public Health System.

The European mHealth Hub will produce a set of Knowledge Tools (KT), providing advice/guidance on large-scale implementation of mHealth services and interventions.

For this Knowledge Tool 1 about **health apps assessment frameworks**, the European mHealth Hub has taken stock of existing health apps assessment frameworks (AFs) actively used in European countries.

The EU eHealth Network will be the major **target audience** for this tool, serving as disseminator Europe-wide. Nevertheless, other policy makers, public authorities, regulators, healthcare providers, developers, healthcare professionals and patients/consumers representatives might also find this tool helpful.

This final report describes the work developed for this KT1, regarding methodology, results, conclusions and recommendations for different target audiences.

As **antecedents**, this tool builds on the work previously conducted by the *EC Working Group on mHealth assessment guidelines* during 2016 and 2017 and the "*Report on the mHealth Assessment Frameworks*"[1], developed in 2018 by WHO/ITU Hub team and other experts.

The main **objectives** of this Knowledge Tool are: 1) To offer an overview of health apps assessment frameworks and repositories in Europe; 2) To assist European countries and regions in the development, improvement or adoption of an assessment framework for health apps at large-scale level; 3) To provide grounds for mutual recognition between frameworks or common assessment components to be used or adopted from a cross-border perspective; 4) To outline some key features on how the mHealth market works, as well as to share some

[1] *Report on the mHealth Assessment Frameworks,* May 2018. Contributors: Meghan Bradway, Eirik Arsand, Konstantinos Antypas, Per Hasvold, Jennifer Lee, Natalia Wroblewska. (21 pages)

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examples of patient organisations in Europe regarding their involvement in the field of health apps quality.

Additionally, KT1 has potential to build connections with the countries' needs derived from the COVID-19 outbreak. Finally, just to clarify that the intention of this report is not to make an individual judgement for each AF, but to put them in "dialogue" and promote learning exchange.

The **methodology** followed by the European mHealth Hub research team comprises several steps: an in-depth desk research to identify relevant assessment frameworks (AFs) and define their key evaluation domains and criteria, collection and analysis of AF data based on the desk research but also by input from the AF owner. This consisted of a validation step where the majority of AF owners provided feedback on the case study files, and a first webinar in June 2020. This approach was complemented with other actions, such as the analysis of health apps repositories -usually created as product of an AF-, a brief study on the role of patient organisations in Europe in this topic, and the inclusion of some additional insights about mHealth market.

During 2021, the work was completed with the following elements: the development of Hub orientations when setting up and developing an AF; a compilation of 27 aspects in which AF(s) could be enriched; a selection of innovative insights that constitutes learnings from the existing AFs; a proposal for mutual recognition based on levels of criteria coverage within the analysed AFs. All these materials were the basis to elaborate the report, as well as the web-based content[2],the visualizations and dissemination materials, and the Hub Talks (webinars 4 and 5)[3].

The methodology has been informed by existing work in the field. In 2016, the European Commission created a *Working Group on mHealth Assessment Guidelines*[4]. Through consultation with different stakeholder groups, the Working Group published a final report[5] where they agreed on the relevance of six criteria, with additional insights for other criteria. On the other hand, the 2018 *Report on the mHealth Assessment Frameworks*[6], where part of the

[2] https://mhealth-hub.org/work-areas#anchor1

[3] https://www.youtube.com/watch?v=y1-1lCeSOFo and https://www.youtube.com/watch?v=haaOly2-Olo

[4] https://ec.europa.eu/digital-single-market/en/news/call-expression-interest-establishing-working-group-mhealth-assessment-guidelines

[5] https://ec.europa.eu/digital-single-market/en/news/report-working-group-mhealth-assessment-guidelines

[6] Report on the mHealth Assessment Frameworks, May 2018. Contributors: Meghan Bradway, Eirik Arsand, Konstantinos Antypas, Per Hasvold, Jennifer Lee, Natalia Wroblewska.

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Hub team participated, was structured according to a set of thirteen criteria for health apps assessment, based on the prior work by the Working Group. For this report, two of the thirteen mentioned domains have been merged (Usability and User Experience), and each of the 12 resulting domains[7] has been split for the analysis into different more specific criteria. The final set contained twelve domains, each with several relevant criteria

The following **24 frameworks** were considered for KT1 and analysed during 2020[8]. The research team prioritized AFs that are active and/or implemented in real settings. While in the beginning most of the AFs considered were available in English, other relevant initiatives available in most spread European languages were also included, given that the information was translatable by the research team. Other inclusion criteria were transparency (minimum information available), evidence-based and trusted sources.

Assessment Framework	Organization	Location
Initiated, led or supported by governmental institutions		
Safety and Quality Strategy in Mobile Health Apps	Andalusian Agency for Healthcare Quality (ACSA)	Andalusia (Spain)
Accreditation Service and TICSS guarantee certification	TIC Salut Social Foundation	Catalonia (Spain)
Digital Assessment Questions (DAQ)*	NHS Digital	United Kingdom
mHealthBelgium	Belgian Federal Government (Multistakeholder initiative; platform operated by Agoria and beMedTech, in cooperation with FAMHP, NIHDI, eHealth Platform)	Belgium
MySNS Selecçao	SPMS - Shared Services of the Ministry of Health, EPE	Portugal
Evidence Standards Framework for Digital Health Technologies	National Institute for Health and Care Excellence (NICE)	United Kingdom
Good practice guidelines on health apps and smart devices	High Health Authority (HAS)	France

[7] Privacy, Transparency, Safety, Reliability, Validity, Interoperability, Technical Stability, Effectiveness, Accessibility, Scalability, User experience/Usability, Security

[8] The Website is open to inclusion of other AFs, as it was the case with DIGI-HTA (Finland) https://mhealth-hub.org/assessment-frameworks

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App Check (DiaDigital and PneumoDigital)	Center for Telematics and Telemedicine (ZTG GmbH)	Germany
Criteria catalogue for self-declaration of the quality of health apps	eHealth Suisse - Swiss Competence and Coordination Centre of the Confederation and the Cantons	Switzerland
MindApps.dk: apps for mental health **	Centre for Telepsychiatry, Region of Southern Denmark	Region of Southern Denmark (Denmark)
PAS 277:2015 Health and wellness apps – Quality criteria across the life cycle – Code of practice	Published by the British Standards Institution (BSI) and sponsored by Innovate UK	United Kingdom
AppKRI (meta-catalogue of criteria)	Fraunhofer Institute for Open Communication Systems (FOKUS) (Project funded by the Federal Ministry of Health)	Germany
AppQ	Bertelsmann Stiftung (funded by the Federal Ministry of Health)	Germany
BfArM DiGA-Fast-Track and Guidance Document	Federal Institute for Drugs and Medical Devices (BfArM)	Germany
GGD AppStore	Association of Regional Public Health Services (GGD) and Regional Medical Emergency Preparedness and Planning (GHOR)	Netherlands
Non governmental initiatives		
ORCHA Review process	Organisation for Review of Care and Health Apps ORCHA	United Kingdom
My Health Apps	PatientView	United Kingdom
ISO/TS 82304-2 Health and wellness apps - Quality and reliability	CEN/TC 251 and ISO/TC 215	Worldwide
iSYS score	iSYS Foundation	Catalonia (Spain)
DEKRA Certification - MEDAPPCARE	Meddappcare (Dekra Group)	France
Our Mobile Health ***	Our Mobile Health	United Kingdom
cMHAFF: Consumer Mobile Health Application Functional Framework	Health Level Seven International (HL7)	International
Continua Design Guidelines (CDG)	Personal Connected Health Alliance (PCHA)	International
Report of the Working Group on mHealth Assessment Guidelines	European Commission	European

* The way apps and digital tools are assessed for use by the NHS has changed. Now the framework is named "Digital Technology Assessment Criteria for health and social care (DTAC)", the new national baseline criteria for digital health technologies entering into the NHS and social care, created in 2021. https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/

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** Website currently under maintenance. Operators have decided to give mindapps.dk a short break so they can relaunch it in a new format around October 2021.

*** Website is not active

The AFs were investigated on a qualitative basis, encompassing two main aspects: i) analysis of AF against evaluation criteria grouped into domains; ii) descriptive analysis of contextual information about the AFs.

Results[9] about evaluation domains and criteria for health apps

Privacy:

1. Domains of privacy and security are in many cases not addressed separately but rather jointly.
2. Differentiation between protection of personal data from unauthorized access (e.g., loss, theft) or misuse and secured against breaches is often not made.
3. The consent of the user with the data collected by the mHealth solution is put to the forefront.
4. Most of the frameworks don't address the use of analytics.

Transparency:

1. The focus of the assessment in the domain of transparency is put on the fact whether the user is informed about what information they are giving to the app, and how the information is used and managed.
2. Distinction between who is distributing, financing, and developing the mHealth app creator/owner is often not assessed/captured by the frameworks.
3. Users are often not informed about algorithms and underlying datasets used to analyse their data.

Safety:

1. Often there is a general assessment of safety but not much detail is given.
2. Every criterion under Safety domain was, at least once, present on the frameworks assessed.
3. National and regional frameworks address more criteria for the Safety domain than international ones.
4. User input validation was the least reported criterion and the most reported one was content quality in terms of clinical validity.

[9] Further specific results about repositories, qualitative insights, June webinar, reimbursement, patient organisations experiences or market considerations can be found in the report.

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Reliability:

1. Most frameworks don't consider reliability analysis/assessment.
2. Specific reliability assessment tools are overlooked across the board.
3. Some frameworks use the term "reliability" without referring to the criteria defined.

Validity:

1. Validity is only addressed in half of the frameworks.
2. Where validity is assessed, the focus is whether the information is backed by health professionals/clinicians/health authorities, and in validation from literature.
3. Comparisons with control groups and validation of information from external hardware/equipment are less assessed.

Interoperability:

1. The majority of the reviewed assessment frameworks does not cover the domain of interoperability at all.
2. The data formats (e.g., standards like XML, or JSON) used for import/export and transmission to different information systems (e.g., EHR) and interpretability of sent/received data is often not addressed.
3. Open, transparent and harmonised standards for data sharing is often not addressed. Additionally, semantic interoperability in terms of use of standardized vocabularies, code lists, and terminologies is not considered.

Technical stability:

1. It is important that the assessed application can maintain its level of performance and have consistent technical functionality.
2. To ensure that the app can maintain its level of performance, it is important to do testing in the conditions of the sudden increase in the number of users and the sudden increase in the amount of data (load test, stress test).
3. The most covered technical stability criterion is covered in less than 50% of assessed frameworks.
4. Regular application monitoring, tracking the number of app crashes and uptime, and updating FAQ regularly should all be standard and mandatory.
5. Technical stability is partly covered in other criteria such as technology criteria, technical design, even security, data privacy, and usability.

Effectiveness:

1. Effectiveness is of the utmost importance for assessing the product (app) itself.
2. Most of the frameworks check whether the application is evaluated against any claimed health benefit or improved health outcome.
3. It is important to point out the risks and side effects that can be caused using the application.
4. It is important to measure whether the desired or intended result of the application usage has been achieved (e.g., improved health outcome).
5. Ethical issues are not always directly addressed or labelled as ethical issues in the AFs.

Accessibility:

1. Different levels of depth in addressing accessibility.

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2. Only a few frameworks mention reasons or specific aspects of accessibility.
3. Frameworks mostly refer to "universal design guidelines", to standards provided by the International Organization for Standardization, or they mention that techniques to ensure accessibility should be used. However, the frameworks often fail to mention concrete design or evaluation criteria.
4. Transparency, in the sense of making transparent the existence of limitations for accessibility, is covered in several frameworks.
5. Standards/guidelines for usable development (which indirectly include those with disabilities or limited cognitive ability, as usable development is targeted to understand user needs of all stakeholder groups) are frequently referred in the frameworks. However, only a limited number of frameworks refer to the specific criteria for accessibility. In addition, many frameworks, standards and guidelines refer to data accessibility or safety and security rather than accessibility in terms of interface design or varying abilities or literacy among user groups.

Scalability:

1. This domain is the least observed.
2. The focus on this subject is connection and interaction with other services and devices.

User experience and usability:

1. Different levels of details in addressing usability.
2. Human factors in user experience.
3. Consideration of the user context.
4. Suggested methods for user experience testing.
5. The user interface experience.

Security:

1. On the analysed frameworks, the focus of security usually lies on privacy.
2. Fewer frameworks evaluate the technical side of security.

Conclusions and recommendations about evaluation domains and criteria

Domain	Conclusion	Recommendations
Privacy	1. Majority of the reviewed AFs address privacy. This can be viewed as a successful effort of law and policymakers, focused to ensure the privacy of the personal health data. On the other hand, well-defined data sharing for the patient benefit must be possible even across borders.	1. The assessment domain of privacy and security should be addressed clearly and separately.
		2. Analytics applied to the patient's data should be disclosed and assessed.
		3. Address a concise and clear definition of privacy for AFs as well as for the user.

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Domain	Conclusion	Recommendations
Transparency	2. The domain of transparency is addressed by most of the reviewed AFs. However, the degree of detail to which the user must be informed varies. What information is handed over to the app, which interests are included by stakeholders and how algorithmic app components deal with the available information is often not sufficiently covered.	4. A clear and concise description of collected and processed information for the user
		5.A clear statement about the stakeholders involved in an mHealth application
		6. Basic but concise information about data processing algorithms must be provided for all the stakeholders
Safety	3. Few details are given on the generality of frameworks about what consideration they have in terms of safety	7.Create a clear distinction on what is safety and security and create a separate topic for safety focusing on clinical safety.
		8. Put development efforts on addressing patient clinical safety.
		9. On connecting services with devices, there is a need for the health institutions, such as healthcare providers, to assess also the safety of the service. This might be applied for contracting developers to create these services.
	4. International AFs don´t pay as much attention to safety than national/regional ones	10. Safety is an important subject that protects the user against harm of using the application and must be a redesign subject in international frameworks
	5. User input validation is not addressed in most frameworks	11. Safety on user input is a growing concern and needs to be considered on every framework. With the advancement of sport trackers, digital scale readings, and the amount of health data generated by the user, it is important to verify that some validation to it is done.
Reliability	6. Despite a few instances refer directly to Reliability, national and regional frameworks analyse reliability in more depth, this might be due to the close relation of these organizations with the citizens.	12. A more concrete approach on defining assessment questions can be a beneficial step on the broader frameworks
Validity	7. There is room for improvement on Validity. Validity also leads to consistency and reliability of the data presented to the user, benefiting the developers and the user itself for a quality product in accordance with the standards and the latest scientific information available.	13. Frameworks across the board might advocate for more validity. This is especially true for clinical validity and to assess that the sources of clinical information are up to date. This ensures also to build up on other domains such as safety and reliability.
		14. Health data which serves as a basis for the mHealth solution must be checked and validated using up to date materials.

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Domain	Conclusion	Recommendations
Interoperability	8. Interoperability is of major importance whenever a mHealth application is supposed to be used in the context of a larger system-of-systems. To enable the inclusion and improve the maintenance of the needed communication interfaces a documented exchange format and documentation on the used nomenclature is paramount. In this context, the implementation of harmonized/standardised communication formats and terminology is preferred. Interoperability will also be of vital importance in supporting the creation of a European Health Data Space.	15. The AF might put the topic of interoperability in the right context e.g. using/referencing the EIF-Interoperability layers, I.e. to exchange information, to be integrated with professional systems, to enable scalable solutions, interoperability is of major importance. All should be aware that for complex health services integration of the mHealth app with other systems it might be necessary.
		16. The AF might reference to existing frameworks/organisations that provide solutions for standardised communication interfaces and terminology.
		17. The assessment framework might demand that the health apps disclose the data model and services to facilitate an interface with the app.
Technical stability	9. None of the existing frameworks covers the Technical stability criteria fully (all sub-criteria included).	18. It is important that the assessed application can maintain its level of performance and have consistent technical functionality. Consider including Technical stability criteria into your framework.
		19. It is important to do detailed performance testing (load test, stress test, spike test, etc.) and have evidence of it.
		20. Regular application monitoring, tracking the number of app crashes and uptime, and updating FAQ regularly should all be standard and mandatory.
Effectiveness	10. Effectiveness is addressed in more than 50% of the AFs, but only a few AFs fully cover the effectiveness domain (in terms of having all the criteria covered).	21. It is important to check whether the app is evaluated against any claimed health benefit or improved health outcome, and what are the potential risks and side effects of using the application.
		22. It is important to point out and assess the risks and side effects that can be caused using the application.
		23. It is important to measure whether the desired or intended result of the application usage has been achieved (e.g. improved health outcome).
		24. More explicit reference to key ethical concepts should be included in the design of mHealth apps.

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Domain	Conclusion	Recommendations
Accessibility	11. The understanding of the term "Accessibility" varied across frameworks. Text or image readability/size were mentioned, but beyond general design guidelines, not many recommendations or further input was found.	25. Guidelines or standards would be of value to ensure accessibility in health app-related context of use, to bridge a common understanding of the design for such apps. In health environments, it is especially important to adequately include all potential target users.
Scalability	12. Although very important, scalability is only seen in terms of connection to other services and devices. Not much attention is giving to a process of expansion of services to other geographies and cultures.	26. Frameworks need to account also for the expansion process of an mHealth solution, either from a start up to a wider application, or from a mature regional application to an international setting.
User experience/Usability	13. User experience and/or usability was addressed by approximately half of the AFs, a few in a detailed way with public usability criteria and metrics, others at a general level. Several AFs mention ISO-standards and certification.	27. Frameworks need to provide the criteria, justification and guidelines publicly available. These elements would provide developers, users and authorities with useful information to apply and assess health apps.
Security	14. There are few frameworks that evaluate the security in terms of technical aspects.	28. Incorporating some depth in the analysis of security is a need and subjects such as network security and communication protocols should be evaluated to include it in the assessment process in frameworks. This allows to build up also on privacy and reliability domains.

There is much heterogeneity among the *22* ***health apps repositories*** identified, when it comes to their features (i.e., size, connection with assessment or quality process, interface development). AFs owners should work more intensely on developing repositories with helpful tools for the reader, as a facilitator for increasing the mHealth adoption

Regarding ***qualitative insights***, both governmental and non-governmental organisations are involved in the creation and maintenance of AFs, which are carried out at national and/or regional levels. While most owners aim to update their frameworks according to the most current regulatory and legislative aspects, this varies greatly between AFs (between one and three years) and only few of them managed to achieve this aim until now.

Several AFs receive world-wide applications and have content available in English, but some are limited by the language of the app. While most frameworks operate on a voluntary basis, only a few of them are of mandatory nature, therefore not contributing to integration within the healthcare system. Incentives should be in place to ensure that the apps developed are interoperable and can be integrated into existing health systems and services.

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The frameworks mainly aim to increase confidence regarding the use and adoption of health apps. The assessment process provides several benefits to app developers. However, these benefits are not present in all the AF and they vary to a great extent. Clear communication about the benefits is therefore key to the AF's wider adoption. Cooperation across AFs could benefit greatly their uptake and attractiveness for developers.

Several frameworks have a clearly defined process and steps that an app developer must follow to submit their app. The complexity of the process varies greatly between frameworks and sometimes within the same framework for different types of apps. While some frameworks require both self-assessment and owner assessment, some are performed by the AFs owners or designated experts. Few frameworks are intended as guidelines and can serve for app developers as self-assessment or can be used for as a third-party guideline for commissioners and other interested stakeholders. The assessment process varies to great extent (between a week and up to three-six months). While few frameworks are transparent about the time, some do not mention at all the required period. It is therefore important to app developers to have a clear understanding of the expectations, the evaluation process, the roles, timing or costs.

Patient organisations have health apps on their agenda and are interested in how self-management and the everyday life of their members can be supported. However, challenges regarding safety and reliability were addressed in the interviews, particularly related to data storage and privacy, and also lack of transparency, accreditation, reliability and validity.

Challenges currently faced by patient organisations include the conventional organisation of health services that does not specifically include mHealth as a core element, and how to make health apps become a structural part of it.

Some of the patient organisations choose to present apps in a generic way and highlight important factors to consider when selecting apps for personal use (individual decision). On the other hand, user-involvement and co-design were mentioned as relevant methods. However, it is not enough to engage one single patient once in the development.

Considering the Hub orientations provided in this report, the following ***steps and key considerations*** can be considered in setting up an assessment framework and evaluation process:

1. Define the scope of the assessment framework
   - Perform a needs assessment.
   - Stakeholder involvement and consultation.
2. Decide on the types of apps to be covered
   - Consider how are health apps legally defined in the country in terms of scope.
   - Flexible approach to the assessment process, according to the level of app complexity.
   - Consider elements such as the language and other country specific facts.

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- Consider what type of evidence related to the apps is needed for the use or classification of the apps for certain purposes.

3. Involve experts

- Involve the experts and organisations according to the defined objectives.
- Consider adding new organisations/stakeholders.

4. Decide on assessment domains and criteria

- While certain criteria should apply to all frameworks use-cases (e.g., security and privacy), others might depend on the classification of the app type and requirements.

5. Define workflow for the assessment process

- Self-assessment performed by the app developers.
- Expert assessment.
- Specific phases/blocks of assessment can be defined.

6. Consider regularly updating the assessment framework

- Reviewing the AF in the light of new regulations and standards.
- Refining/enriching the framework criteria based on experience and lessons learned.

7. Funding/business model process to ensure sustainability of the assessment process

- Evaluation of costs necessary to set up the assessment process: costs of platform maintenance etc.
- Partnerships.
- Sustainability pathways and business models that might be considered: public funding; perceived fees; yearly fees.

8. Interface/Digital health libraries or repositories

- Technical implementation of the library (hosting, website layout, etc).
- Language and scope.
- Transparency of the assessment process for all stakeholders.
- How the repository is updated and maintained.
- Information about apps (listing app functions, who is supporting the app etc.).
- Search filters for easier navigation
- Clear process for delisting or archiving apps.

9. Ensure adoption by the stakeholders

- Dissemination and communication aspects.
- Trainings with healthcare organisations and healthcare professionals.

10. Encourage reflexive learning

- What worked, what didn't, adapting the process according to the lessons learned.

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The infographic below provides a non-exhaustive list of ***key aspects to enrich existing health apps AFs***.

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Privacy: creating a *trustworthy environment* is the key to wider adoption of mHealth. One way of achieving this is for the AFs to focus on *how the personal data are managed in terms of access, retention policy and transmission methods.*

Transparency*:* one of the main aspects of transparency is the *accurate information about the way an application handles, transmits, stores and secures user related data. Examples for the secondary use of data, or the connection to open data platforms* are of special interest.

Creating a transparent approach should include full information about the way data is handled, transferred and stored. One way to do so could be the *usability of transparency enhancing tools*.

Safety: *user input information safety* is one criterion that is seldom present, and can be considered an innovative example for the AFs.

Reliability focuses primarily on consistency and stability of results. Other aspects, collected from the analysis, are the *assessment of errors* and *how everything gets logged or documented*. The *data* should be also *evaluated and documented*. *Testing* is also an important part of reliability, but even fewer frameworks address the issue.

It is important to have in mind two main paths to evaluate validity: the *validity in terms of where the information is gathered and supports the content of the app*, and the *validity in terms of accountability to the information that supports the app*. Some AFs assess the *level of liabilities* for the information provided. Only a few AFs are concerned with very clearly indicate the user to *refer to their physician,* as one relevant element in reliability.

Interoperability: the AFs could include *references to specific harmonized international IT standards*. Furthermore, requirements could focus on *disclosing the used data models and service specifications* to facilitate interfaces with the mHealth app using inter process communication capabilities provided by the operating system.

Technical stability: Necessary *tests* that should be carried out to ensure that the software complies with the identified needs and with the design; *Unit tests; Integration tests*; *Stress tests*; *Penetration tests*.

Effectiveness: Only a few AFs are not focused only on *health benefits* but also ask about *other types of benefits* – economic, behavioral, psychological, social, etc.

Capturing health risks and side effects of mobile applications is very important for patient safety. This criterion can be assessed under effectiveness, patient safety, clinical safety, device safety, quality, risks, but it is important to be assessed. Improvement can be made on *capturing a methodology used to identify possible risks or side effects*. Also, AFs could ask about *measures* that have been *put in place to prevent a recurrence of any reported events*.

Accessibility: *Use of web content accessibility guidelines* (WCAG 2.0). For instance, *mobile accessibility considerations* must be related to the *four accessibility principles*: *(1) perceivable, (2) operable, (3) understandable and (4) robust*.

There are also examples of *techniques that apply to mobile applications*, such as text alternatives, navigation, predictability and compatibility.

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Scalability: where the domain is captured, extensive guidelines exist to apply *interconnection between services*. Inclusion of *assessment of compatibility of apps with different platform configurations*.

User experience/usability: *use of* international standard *ISO 9241-210:2019* (Ergonomics of human-system interaction — *Human-centred design for interactive systems*) to assess the usability of mobile health applications.

Security is one of the most predominant domains in the analysed AFs. Nevertheless, some important details are not so common but equally important, i.e., *if data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, is processed* by the mHealth solution, or app. Usage of very specific criteria from some assessment frameworks, i.e., *threat analysis; assessment of security by design and by default*.

Exploring commonalities and mutual recognition

The fact of having identified at least 24 health apps assessment frameworks and 22 repositories in Europe, is a clear indicator of the large heterogeneity in this field. This diversity has clear consequences on the adoption of mHealth.

During the Hub Talk held on 17 June 2021, 90% of respondents considered that working towards mutual recognition between health apps AFs in Europe was 'very important' or 'important'.

In that Talk, the audience pointed in three different directions for the question "*Could you suggest effective ways of moving forward the goal of mutual recognition between existing health apps assessment frameworks in Europe?*":

- *Communication, knowledge exchange and collaboration between AFs*
- *Mandatory requirements, core criteria or a general framework*
- *Regulation and standardisation*

Responding to EC's interest on this issue, the European mHealth Hub has developed the first steps of an approach for commonalities and mutual recognition graded in three intensity levels, according to the outcomes of criteria coverage shown in Annex 4.

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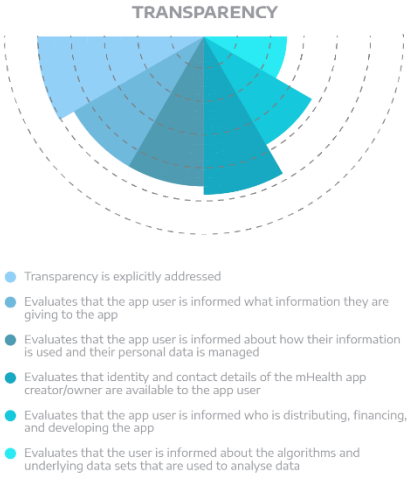
12 assessment domains • Privacy • Transparency • Safety • Reliability • Validity • Interoperability • Technical stability • Effectiveness • Accessibility • Scalability • User experience / usability • Security	5-8 criteria analysed per domain (See Table **3**. Evaluation domains and criteria) Visualizations (Annex 4)  	Intensity **level 1 >83%** *Criteria considered at least in 20 out of 24 AF* Intensity **level 2 66%-83%** *Criteria considered in 16-19 out of 24 AF* Intensity **level 3 50%-66%** *Criteria considered in 12-15 out of 24 AF*

The first of these intensity levels could be considered or adopted by countries or regions as common grounds when building their own AF. The additional levels could be added on top of that, based on specific national or regional needs. This most intense level could also help as guidance or starting point for mutual recognition across existing AFs.

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1. Introduction

The **European Innovation and Knowledge mHealth Hub** (https://mhealth-hub.org/) is a project established by the International Telecommunication Union (ITU), in partnership with the World Health Organization (WHO) and the Regional Ministry of Health of Andalusia (Spain) to support the integration of mHealth programmes and services into the national health systems of European countries.

The Hub project is funded by the European Commission under the Horizon 2020 program and is underpinned by a consortium of 17 public and private partners[10] from 12 European countries led by the Andalusian Public Health System.

The European mHealth Hub will produce a set of Knowledge Tools (KT), providing advice/guidance on large-scale implementation of mHealth services and interventions. The topic for the first toolkit (KT1) is **health apps assessment frameworks**.

For this KT1, the European mHealth Hub has taken stock of existing health apps assessment frameworks (AFs) actively used in European countries. The Hub team has conducted a thorough desk research process to gather key information based on publicly available sources. The EC considers the assessment of mHealth as an important topic, and it would benefit from collaboration and exchange of ideas and lessons learnt. At this point, the European mHealth Hub would like to provide a forum for owners of assessment frameworks, with different consultation and dissemination activities, like the first webinar hosted in June 2020.

The EU eHealth Network will be the major target audience for this tool, serving as disseminator Europe-wide. Nevertheless, other policy makers, public authorities, regulators, healthcare providers, developers, healthcare professionals and patients/consumers representatives might also find this tool helpful.

This report describes the work developed for this KT1, regarding methodology, results, and conclusions and recommendations for different target audiences. The draft version has been circulated and disseminated among relevant stakeholders in this field, to get feedback for this final version and set the basis for future collaboration and knowledge exchange.

[10] Campania Region, European Health Telematics Association (EHTEL), empirica Communications and Technology Research, Ericsson Nikola Tesla d.d., Foundation Tallinn Science Park Tehnopol/Connected Health Cluster, Health Center Zagreb –"Centar", HL7 International Foundation, The European Institute for Innovation through Health Data, Mijn Data Onze Gezondheid; Spanish Ministry of Health; Osakidetza - Basque Health Service; Continua Health Alliance Private Foundation (for PCHAlliance); ULSS 4 Veneto Orientale – ProMIS Department; County Council of Jämtland (Region Jämtland Härjedalen); SPMS Serviços Partilhados do Ministério da Saúde, E.P.E.; Centre of eHealth. University of Agder; University of Applied Sciences Technikum Vienna.

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This knowledge tool builds on the work previously conducted by the *EC Working Group on mHealth assessment guidelines* during 2016 and 2017 and the "*Report on the mHealth Assessment Frameworks*"[11], developed in 2018 by WHO/ITU Hub team and other experts.

In the 2018 report, the main goal was the identification of similarities between the frameworks then analysed. The main findings in that work were:

- The report identified three frameworks' categories (assessment, implementation, services[12]). An AF can fall into more than one category. Only frameworks in the "assessment" category were analysed in further detail.
- Large amount of heterogeneity among the AFs assessed, regarding comprehensiveness, depth, format, or target audience of the AF.
- Most frameworks assessed security, privacy, user experience and usability; most frameworks did not assess reliability and safety, and most frameworks targeted developers in some capacity. Some standards were referenced by multiple frameworks. Most frameworks did not reference each other.
- Differences in stakeholder and frameworks priorities: most frameworks did not assess the criteria considered most important by the stakeholders, as interviewed by the Working Group on mHealth Assessment (i.e., transparency, safety, reliability, validity and interoperability).

[11] *Report on the mHealth Assessment Frameworks,* May 2018. Contributors: Meghan Bradway, Eirik Arsand, Konstantinos Antypas, Per Hasvold, Jennifer Lee, Natalia Wroblewska. (21 pages)

[12] *Assessment*: frameworks outlining how to assess an mHealth product; *Implementation*: frameworks outlining how to assess the readiness of the environments to adopt an mHealth product; *Services*: frameworks used by services to provide an assessment of an mHealth product.

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2. Objectives

The main objectives of this Knowledge Tool about health apps assessment frameworks are:

- To offer an overview of health apps assessment frameworks and repositories in Europe.
- To assist European countries and regions in the development, improvement or adoption of an assessment framework for health apps at large-scale level.
- To provide grounds for mutual recognition between frameworks or common assessment components to be used or adopted in a cross-border perspective.
- To outline some key features on how the mHealth market works, as well as to share some examples of patient organisations in Europe regarding their involvement in the field of health apps quality.

The COVID-19 outbreak came when the KT1 was already under development, however the intention is to build bridges to connect this work with the countries' needs on the "new normality" developed.

Finally, just to clarify that the intention of this report is not to make an individual judgement for each AF, but to put them in "dialogue" and extract relevant aspects and learnings for the creation and maintenance of AFs.

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3. Methodology

3.1 Overview

The methodology followed by the European mHealth Hub research team comprises several steps (Figure 1): an in-depth desk research to identify relevant assessment frameworks (AFs) and define their key evaluation domains and criteria[13], collection and analysis of AF data based on the desk research but also by input from the AF owner. This consisted of a validation step where the majority of AF owners provided feedback on the case study files, and a first webinar. The webinar was organized in June 2020 with a part of AF owners (invitation was sent to all of them), where an open discussion took place between the Hub and the owners, touching on several essential aspects of collaboration and future plans.

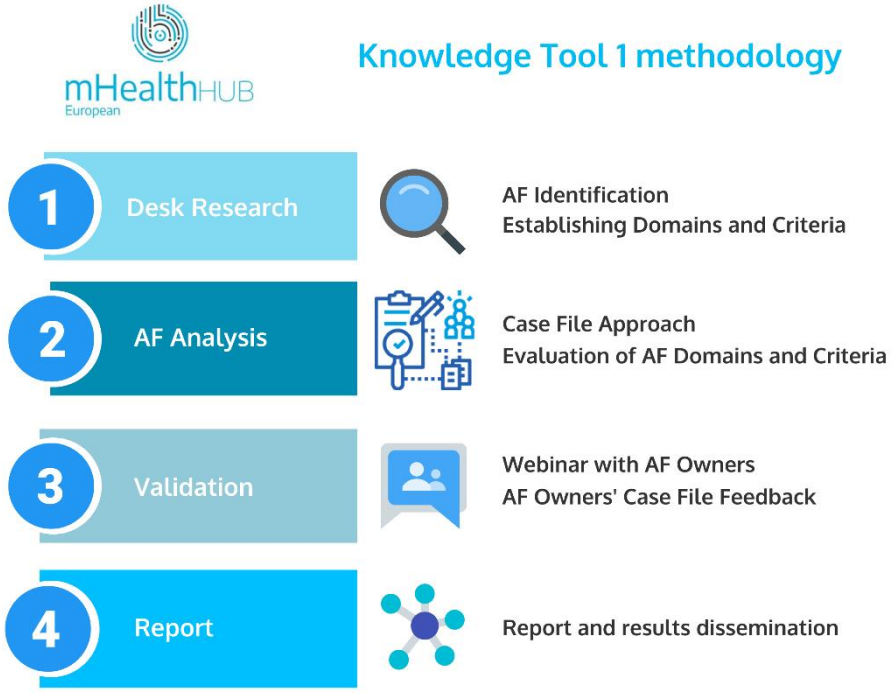

Figure 1- Knowledge Tool 1 methodology

[13] For example, privacy as a domain, and one of its criteria being "the compliance with applicable laws and guidelines is explicitly addressed in the framework" (See table on domains and criteria in the following pages)

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This approach was complemented with other actions, such as the analysis of health apps repositories -usually created as product of an AF-, a brief study on the role of patient organisations in Europe in this topic, and the inclusion of some additional insights about mHealth market.

During 2021, the work was completed with the following elements: the development of Hub orientations when setting up and developing an AF; a compilation of 27 aspects in which AF could be enriched; a selection of innovative insights that constitutes learnings from the existing AFs; a proposal for mutual recognition based on levels of criteria coverage within the analysed AFs.

All these materials were the basis to elaborate the report, as well as the web-based content[14], the visualizations and dissemination materials, and the Hub Talks (webinars 4 and 5) held on June and July 2021 respectively[15].The methodology has been informed by existing work in the field. In 2016, the European Commission created a *Working Group on mHealth Assessment Guidelines*[16] to develop guidelines for assessing aspects such as validity and reliability in health apps. Through consultation with different stakeholder groups[17], the Working Group published a final report[18] where they agreed on the relevance of six criteria[19], with additional insights for other criteria. On the other hand, the 2018 *Report on the mHealth Assessment Frameworks*[20], where part of the Hub team participated, was structured according to a set of thirteen criteria[21] for health apps assessment, based on the prior work by the Working Group. The report

[14] https://mhealth-hub.org/work-areas#anchor1

[15] https://www.youtube.com/watch?v=y1-1lCeSOFo and https://www.youtube.com/watch?v=haaOly2-Olo

[16] https://ec.europa.eu/digital-single-market/en/news/call-expression-interest-establishing-working-group-mhealth-assessment-guidelines

[17] Patients, Healthcare professionals, Industry, Public authorities, Payer and Social Health Insurance, Research and Academia.

[18] https://ec.europa.eu/digital-single-market/en/news/report-working-group-mhealth-assessment-guidelines

[19] Privacy, Transparency, Reliability, Validity, Interoperability, Safety.

[20] Report on the mHealth Assessment Frameworks, May 2018. Contributors: Meghan Bradway, Eirik Arsand, Konstantinos Antypas, Per Hasvold, Jennifer Lee, Natalia Wroblewska.

[21] Privacy, Transparency, Reliability, Validity, Interoperability, Safety, Technical Stability, Effectiveness, Accessibility, Usability, Scalability, User Experience, Security.

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examined the selected assessment frameworks against the established set of criteria to identify common themes and differences in available frameworks.

3.2 Desk research

A desk research was carried out in the period February – May 2020 with the goals of identifying European public and private framework initiatives to be included in the research. The final list contained **24 frameworks**, 15 of which are initiated, led or supported by governmental institutions.

The team focused on identifying assessment frameworks[22] or service frameworks[23], as defined in the 2018 Report. All of them were considered "assessment frameworks" (AFs) in a global sense. The research team prioritized AFs that are active and/or implemented in real settings. While in the beginning most of the AFs considered were available in English, other relevant initiatives available in most spread European languages were also included, given that the information was translatable by the research team. Other inclusion criteria were transparency (minimum information available), evidence-based and trusted sources.

The analysed frameworks can be consulted in Annex 1a, as well as all the case files can be found in Annex 3. A table containing AFs and their organisations is provided below:

Assessment Framework	Organization	Location
Initiated, led or supported by governmental institutions		
Safety and Quality Strategy in Mobile Health Apps	Andalusian Agency for Healthcare Quality (ACSA)	Andalusia (Spain)
Accreditation Service and TICSS guarantee certification	TIC Salut Social Foundation	Catalonia (Spain)
Digital Assessment Questions (DAQ)*	NHS Digital	United Kingdom
mHealthBelgium	Belgian Federal Government (Multistakeholder initiative; platform operated by Agoria and beMedTech, in cooperation with FAMHP, NIHDI, eHealth Platform)	Belgium
MySNS Selecçao	SPMS - Shared Services of the Ministry of Health, EPE	Portugal

[22] Assessment frameworks: these frameworks provide a guideline or a framework on how to assess an mHealth product.

[23] Service frameworks: these frameworks are used by services to assess an mHealth product. The frameworks themselves are often not made publicly available in detail since they often are used by commercial companies.

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Evidence Standards Framework for Digital Health Technologies	National Institute for Health and Care Excellence (NICE)	United Kingdom
Good practice guidelines on health apps and smart devices	High Health Authority (HAS)	France
App Check (DiaDigital and PneumoDigital)	Center for Telematics and Telemedicine (ZTG GmbH)	Germany
Criteria catalogue for self-declaration of the quality of health apps	eHealth Suisse - Swiss Competence and Coordination Centre of the Confederation and the Cantons	Switzerland
MindApps.dk: apps for mental health **	Centre for Telepsychiatry, Region of Southern Denmark	Region of Southern Denmark (Denmark)
PAS 277:2015 Health and wellness apps – Quality criteria across the life cycle – Code of practice	Published by the British Standards Institution (BSI) and sponsored by Innovate UK	United Kingdom
AppKRI (meta-catalogue of criteria)	Fraunhofer Institute for Open Communication Systems (FOKUS) (Project funded by the Federal Ministry of Health)	Germany
AppQ	Bertelsmann Stiftung (funded by the Federal Ministry of Health)	Germany
BfArM DiGA-Fast-Track and Guidance Document	Federal Institute for Drugs and Medical Devices (BfArM)	Germany
GGD AppStore	Association of Regional Public Health Services (GGD) and Regional Medical Emergency Preparedness and Planning (GHOR)	Netherlands
Non governmental initiatives		
ORCHA Review process	Organisation for Review of Care and Health Apps ORCHA	United Kingdom
My Health Apps	PatientView	United Kingdom
ISO/TS 82304-2 Health and wellness apps - Quality and reliability	CEN/TC 251 and ISO/TC 215	Worldwide
iSYS score	iSYS Foundation	Catalonia (Spain)
DEKRA Certification - MEDAPPCARE	Meddappcare (Dekra Group)	France
Our Mobile Health ***	Our Mobile Health	United Kingdom
cMHAFF: Consumer Mobile Health Application Functional Framework	Health Level Seven International (HL7)	International
Continua Design Guidelines (CDG)	Personal Connected Health Alliance (PCHA)	International
Report of the Working Group on mHealth Assessment Guidelines	European Commission	European

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* The way apps and digital tools are assessed for use by the NHS has changed. Now the framework is named "Digital Technology Assessment Criteria for health and social care (DTAC)", the new national baseline criteria for digital health technologies entering into the NHS and social care, created in 2021. https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/

** Website currently under maintenance. Operators have decided to give mindapps.dk a short break so they can relaunch it in a new format around October 2021.

*** Website is not active

Table 1. Analysed assessment frameworks and their organisations

The report aims to provide a state-of-the-art overview of health apps assessment frameworks and repositories in Europe. Even with the extensive outreach of the Hub partners, some newly emerging frameworks and repositories might not have been included by the team due to no or little available information at the time of the desk research. The Hub is committed to continuously updating the landscape and will consider for inclusion any new framework or repository brought forward by Hub members or through other channels, such as the Hub website[24].

The majority of AFs described in this report have been directly informed by the AF owners. The Hub is actively seeking contact with all AF owners to ensure that the information presented is validated by them and new developments are correctly represented.

3.3 Frameworks' analysis

The AFs were investigated on a qualitative basis, encompassing two main aspects:

- analysis of AF against evaluation criteria grouped into domains, using a dedicated Spreadsheet assessment tool, and,
- descriptive analysis of contextual information about the AFs, such as target audiences, geographical scope, details about their business models, etc. Contextual information was collected via case files.

[24] The Website is open to inclusion of other AFs or repositories, as it was the case with DIGI-HTA (Finland), Helsenorge Verktøykatalog (Norway), or Mind Platform (Netherlands) https://mhealth-hub.org/assessment-frameworks and https://mhealth-hub.org/health-apps-repositories-in-europe

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The outcomes of such analysis have allowed to develop specific pieces of information, product-oriented, like the visualizations, Hub orientations, innovative insights, aspects to enrich AFs, or the proposal for mutual recognition.

3.3.1 EVALUATION DOMAINS AND CRITERIA

The methodology followed by the research team advances previous findings with an in-depth analysis of the elements considered relevant for health apps assessment (evaluation criteria grouped into domains), the processes of assessing and recognising health apps as compliant with the framework, and the implications for a potential common European approach to health apps assessment. For this report, two of the thirteen mentioned domains have been merged (Usability and User Experience), and each domain has been split for the analysis into different more specific elements. The final set contained twelve domains, each with several relevant criteria (here domains replace criteria as in the 2018 Report and criteria are considered sub-elements).

Domain	Definition
Privacy	The framework considers whether apps comply with all applicable laws and guidelines (i.e., General Data Protection Regulation (GDPR), ePrivacy Directive). It requires that personal health data are protected from accidental or malicious data privacy breaches and that data are processed only on the basis of a valid legal base (i.e., consent).
Transparency	The framework requires that users understand what information they are giving to the app, how their information will be used, and who is distributing, financing, and developing the app. These requirements include (but are not limited to): the identity and contact details of the controller (i.e., the mHealth app creator/owner), the recipients or categories of recipients of the personal data, the period for which the data will the stored, and the method by which personal data will be transferred.
Safety	Ensuring the mHealth solution does not cause any harm to the users, be it of physical, mental, social, or financial nature. Note: ties with reliability/validity.
Reliability	The framework considers whether the app is consistent in its functions. It should consider the app's ability to produce repeatable and reliable results (i.e., does the app always give the same results given the same set of parameters). Note: Technical stability is a necessary but insufficient factor for reliability (content).
Validity	The framework considers whether the app utilizes scientific literature and medical expertise in the clinical validation phase of an app (i.e., is the "product" provided by the app evidence-based?).
Interoperability	The framework considers factors including but not limited to whether: (1) the mHealth solution can function on multiple platforms; (2) the data can be exported in multiple formats and transmitted to different information systems (such as electronic health records); (3) the data is both computer interpretable and human understandable.

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Technical stability	The framework considers the app's ability to maintain its level of performance under stated conditions for a stated amount of time. Consistent technical functionality may be supported by provisions such as a regularly updated FAQ for users or regular monitoring of software for bugs. Note: overlaps with reliability
Effectiveness	The framework considers whether the app is evaluated against any claimed health benefit or improved health outcome. Does the app fulfil its intended function for the user? Factors contributing to effectiveness include: (1) Evidence of clinical benefits and cost-effectiveness of its mHealth solution (i.e. peer-reviewed studies and trials); (2) A measure of desired or intended result in every-day use and particular environments; (3) The capacity to reach the target population with minimum resources invested to improve general health of the population.
Accessibility	The framework considers whether all users of the app's target group are able to use it. Where there are limitations, the app should make them transparent (i.e., the app should make clear if it is not usable for persons with low vision and take steps to mitigate problems if possible). Frameworks should consider national, EU and international laws and guidelines for those with disabilities or limited cognitive ability.
Scalability	The framework considers whether the app is able (when it should) to scale to a certain size without compromising key app elements including but not limited to privacy, security, and usability. For example, the framework should consider whether the app/app developers have strategies to handle increasing data volume. ***Note***: additional input for the definition, produced by members of the research team in 2020: Scalability means the potential to address millions of people to impact positively on their health. The app shall not just promote specific products but should provide cross-cutting health content and technical support to be incorporated into other applications. It works to develop the broader ecosystem within which a national mHealth programme will sit, helping ensure that it is integrated with other health services. In doing so, each programme becomes a sustainable part of the health system whilst also helping to promote health and wellbeing around the world. Scaling-up shall cover all income groups and disease priorities and shall be based on WHO Handbooks on implementation and WHO mHealth MAPS toolkit.
User experience / usability	*User experience*: the framework considers whether the app takes into account a person's holistic experience (i.e., physical, cognitive, emotive, beliefs, preferences, or behaviours) using a particular product, system or service. Does the app consider the user, the system and the context of use? *Usability*: The framework considers whether the app facilitates ease of use for the widest user base possible, taking into account different physical or mental abilities or impairments (where relevant) as well as level of comfort, engagement with and adherence to the app.
Security	The framework considers whether personal health data is stored, transferred, and managed securely (i.e., the app uses up-to-date security standards and

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	considers cybersecurity capabilities in line with EU's NIS Directive[25]). The framework confirms that the app does not require more information than needed for the purpose of the app.

Table 2. Domains' definitions

For each domain, the team elaborated specific criteria of relevance from a European mHealth perspective, applying the insights from the desk research, alignment with key documents such as the GDPR, and the partners' own background and experience in the field. The set of domains and criteria was shared with ITU and WHO technical teams in the Hub project to get their feedback for a final version. Each domain included between five and nine specific criteria.

The evaluation was performed in Microsoft Excel, providing the research team with all information necessary to evaluate the AFs:

- The list of all frameworks to be analyzed, including contact details.
- Individual sheets per AF containing all domains and criteria to be assessed. Each sheet requires an assessment per criterion based on three options indicating whether the AF covers the criterion (yes, somewhat, no) and a comments/references field to elaborate on the evaluation.
- A visual summary of the evaluation progress, aiding the Hub partners in the regular online meetings accompanying the AF analysis.

As different team members were responsible for the assessment of different domains based on their expertise, the spreadsheet allowed for simultaneous work on all AFs by all team members.

Before the analysis, a small pre-test was carried out, aiming to finalize the criteria based on the evaluation of few AFs. The final set of domains and corresponding criteria is provided in the table below.

Domain	Criteria
Privacy	1. Privacy is explicitly addressed in the framework (e.g., dedicated section, or at least one compliance question) 2. Compliance with applicable laws and guidelines (i.e., General Data Protection Regulation (GDPR), ePrivacy Directive) is explicitly addressed in the framework

25 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.194.01.0001.01.ENG&toc=OJ:L:2016:194:TOC

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	3. National and local laws, policies and guidelines are explicitly addressed in the framework or the framework requires the app to state which laws, policies and guidelines are implemented 4. Protection from unauthorized access (e.g., loss, theft) or misuse of personal data that is collected, stored, processed, or communicated is explicitly addressed in the framework (e.g., stored and sent encrypted) 5. Requirements that patient's health information that is collected, stored, processed, or communicated is properly secured against breaches are explicitly addressed in the framework 6. Handling of patient data with consent and legitimate interest is explicitly addressed in the framework. Questions about what data the apps have access to, what data needs to be communicated with other apps and where will the data be stored are covered. 7. The framework explicitly addresses how analytics can be used.
Transparency	1. Transparency is explicitly addressed in the framework (e.g., dedicated section, or at least one compliance question) 2. Explicitly addresses that the app user is informed what information they are giving to the app 3. Explicitly addresses that the app user is informed about how their information is used and their personal data is managed in terms of access, retention policy, and transmission methods) 4. Explicitly addresses that the app user is informed who is distributing, financing, and developing the app 5. Explicitly addresses that the identity and contact details of the mHealth app creator/owner are available to the app user 6. Explicitly addresses that the user is informed about the algorithms and underlying data sets that are used to analyse data. (Algorithmic transparency, explainable AI).
Safety	1. Safety is explicitly addressed in the framework (e.g., dedicated section, or at least one compliance question) 2. Explicitly evaluates if the app poses Clinical Risk 3. Explicitly evaluates the content Quality in terms of clinical validity and quality 4. Explicitly evaluates that a report on safety concern is done 5. Explicitly evaluates that safe communication (encrypted) of data is done 6. Explicitly evaluates user input validation (this can include external hardware validation)
Reliability	1. Reliability is explicitly addressed in the framework (e.g. dedicated section, or at least one compliance question) 2. Explicitly evaluates if a system of interrater reliability is used 3. Explicitly evaluates if a test-retest reliability method is used 4. Explicitly evaluates whether the app is consistent in its functions. 5. Explicitly evaluates the app's ability to produce repeatable and reliable results (i.e. does the app always give the same results given the same set of parameters).
Validity	1. Validity is explicitly addressed in the framework (e.g., dedicated section, or at least one compliance question) 2. The framework considers whether the app utilizes scientific literature and medical expertise in the clinical validation phase of an app 3. Explicitly evaluates if a comparison of the exchanged data with control group or medical literature is made

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	4. Explicitly evaluates if medical data and information is backed by health professionals/Clinicians/health authorities 5. Explicitly evaluates that if external hardware is used to get data, the measurements are validated in terms of content and construct. 6. Explicitly evaluates if a validation protocol is in place.
Interoperability	1. Interoperability is explicitly addressed in the framework (e.g., dedicated section, or at least one compliance question) 2. Published data formats (e.g., standards like XML, or JSON) for import/export and transmission to different information systems (e.g., EHR) are explicitly addressed in the framework. 3. Function of the mHealth solution on multiple platforms is explicitly addressed in the framework 4. Interpretability of sent/received data is considered from both computer and human perspective based on used terminology and included, contextual information. 5. Open, transparent, and/or harmonised standards for data sharing are explicitly addressed in the framework 6. Considers semantic interoperability in terms of use of standardized vocabularies, code lists, terminologies
Technical Stability	1. Technical stability is explicitly addressed in the framework (e.g., dedicated section, or at least one compliance question) 2. The application can maintain its performance level in the event of a sudden increase in the number of users or the simultaneous connection of all users of the application 3. An application can maintain its performance level with a sudden increase in the amount of data 4. The application works regardless of device type 5. Application is resilient to OS version upgrade (does not need re-assessment at OS upgrade) 6. Sensitive data is not exposed, and security is not compromised if application crashes (due to any reason) 7. A load test is done for each application upgrade and OS upgrade 8. Application can operate without a cellular network/Wi-Fi (with no risk of data compromise) 9. The application is regularly monitored; there is a track of the number of app crashes and uptime; FAQ is updated regularly
Effectiveness	1. Effectiveness is explicitly addressed in the framework (e.g., dedicated section, or at least one compliance question) 2. The framework can capture what health benefits the assessed app is claiming to have. 3. The framework can capture if evidence about the claimed benefits is available. 4. The framework can capture different levels of evidence (e.g. expert opinion, observational study, randomized controlled trial (RCT), systematic review of RCT's) 5. The framework can capture health risks and side effects. 6. The framework can capture the app's applicability by distinguishing different subgroups (e.g. gender, age, health literacy) 7. The desired or intended result (e.g. improved health outcome) can be measured.

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Accessibility	1. Accessibility is explicitly addressed in the framework (e.g. dedicated section, or at least one compliance question) 2. The framework considers whether all users of the app's target group are able to use it, taking into account different physical or mental abilities or impairments. 3. The framework considers techniques to increase accessibility (e.g. Increasing text visibility, large and simple controls, description of UI elements) 4. Where there are limitations, the app makes them transparent (i.e. the app should make clear if it is not usable for persons with low vision and take steps to mitigate problems if possible). 5. The framework considers national, EU and international laws, web accessibility guidelines and standards for those with disabilities or limited cognitive ability (visual, hearing, impaired speech).
Scalability	1. Scalability is explicitly addressed in the framework (e.g., dedicated section, or at least one compliance question) 2. Explicitly evaluates that there are procedures to easily upgrade the application infrastructure (increase hardware, database scaling) without compromising key app elements (privacy, security, and usability, etc.) 3. Explicitly evaluates that the app has predefined integration interfaces and could connect to other health services without an upgrade 4. Explicitly evaluates that the app can interact with other services (non-health services) 5. Explicitly evaluates that the app can handle different cultures and multiple languages in the process of scaling up
User experience/ Usability	1. User experience is explicitly addressed in the framework (e.g., dedicated section, or at least one compliance question) 2. The framework considers whether the app takes into account a person's holistic experience (i.e., physical, cognitive, emotive, beliefs, preferences, or behaviours) using a particular product, system or service. 3. Does the app consider the user, the system, and the context of use? 4. Was the user experience testing a part of the application testing prior to market release? 5. User interface experience (does the app follow a responsive design, or UX guidelines, was the end user involved in the design of UI?)
Security	1. Security is explicitly addressed in the framework (e.g., dedicated section, or at least one compliance question) 2. Explicitly evaluates that no personal or sensitive user data is logged to the system or app-specific log. 3. Explicitly evaluates that no personal or sensitive data is shared with third parties 4. Explicitly evaluates that all traffic is processed with resource to SSL/TLS 5. Explicitly evaluates that application declares a network security configuration. 6. Explicitly evaluates that cryptographic security is in place (at rest and in motion). 7. Explicitly evaluates that the app could meet all criteria when installed on an older version of OS. 8. Explicitly states in which country the data is stored

Table 3. Evaluation domains and criteria

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Other criteria could have been incorporated in the work of KT1. The criteria were defined according to expertise and experience from the consortium group and reviewed by project peers beforehand. Nevertheless, the European mHealth Hub project members acknowledge that other criteria could be in effect used to evaluate/assess Assessment Frameworks. It is also important to mention that certain criteria overlap in certain domains and that the aim of the project is to include this as a way to demonstrate that several subjects have connections and that assessment is seldom a straight forward task.

3.3.2 CASE FILES

The research team adopted a case study approach designed to analyze contextual information about the AFs which was not included in the domains and criteria spreadsheet. A case file template was developed, with sections describing the following aspects:

- Framework name
- Short description
- Creator and owner
- Owner type
- Contact details
- Year of creation
- Website/Web presence
- Update frequency
- Last update
- Geographical application scope
- Conformity basis
- Target audience(s) and value propositions
- Assessment subject
- Assessment domains coverage[26]
- Process detailing how the assessment framework is to be applied
- How the assessment framework is performed
- Framework's sustainability and business model
- Presentation and visualization of the assessment results

The case files were sent to AF owners for validation. Out of 24 frameworks, a number of 17 (**71%**) received feedback (see Annex 1b). The case files (Annex 3) allowed for a novel cross-comparison of several key issues such as the frameworks' sustainability and business models,

[26] *Considers* = >65% of the criteria within the domain are filled in with "yes". | *Does not consider* = None of the criteria within the domain are filled in with "yes" or "somewhat". | *Somewhat considers* = the rest of situations.

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the assessment processes followed, and the frameworks' conformity basis. All the case files can be found in the Annex 3.

3.4 Assessment frameworks owners input and validation

The AF owners were invited to a webinar, intended as a first one in a series of webinars to be carried out by the Hub under the umbrella of Hub Talks 2021 with the aims of involving this stakeholder group better into the ongoing work, seeking to validate the results and facilitate a forum among AF owners. Another objective of the webinar was to initiate a discussion about common AF elements and approaches and implications for a potential European common approach to mHealth assessment.

Eight AF owners joined (33%) (see Annex 1b) this first webinar hosted by the Hub on 17 June 2020, where an overall explanation on the knowledge tool, its methodology and process were given, and the following topics were addressed to facilitate open discussion and dialogue between AF owners:

- The challenge of health apps becoming part of the health systems. How are the assessment frameworks contributing to it?
- The challenge of having dialogues between assessment frameworks: experiences/ideas about cross-recognition.
- Health apps in Europe. What elements are missing in a European approach for quality and reliability of apps?
- Frameworks future plans and the near horizon of CE-marking.

The outcomes of the webinar can be summarized as follows:

- Progress is being made in initiatives to adapt their frameworks to CE-marking and integrate health apps in the health system (e.g., Germany, some regional initiatives in Spain, like Andalusia or Catalonia), however the process is long and complex.
- The scenario is fragmented, lack of knowledge exchange. AF owners show a willingness to learn from others; commonalities or cross recognition approaches might be an opportunity to make clearer the value and benefits of the assessment process, e.g., to developers.
- The coexistence of global and national or regional linked aspects in the AFs is a challenge when trying to find commonalities or cross recognition elements.
- The importance of monitoring and continuous review, being digital health a changing landscape.
- There are aspects of interest and opportunities to improve quality and learning opportunities beyond the assessment criteria (e.g., providing other practical information helpful for the app user).

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- Some actors have lack of awareness or knowledge about the CE-marking new context and their implications (e.g., some developers, patient organisations, medical associations etc.).
- Ethical issues are not always directly addressed or labelled as ethical issues, but often contained within other criteria in the AFs.

More detailed information can be seen in the Results section: "Insights from the webinar with AFs owners".

The fourth Hub Talk on health apps assessment, hold on June 2021, is another action taken for the involvement of AFs owners in the Hub work. The content presented in that Talk has been included in different sections of this report.

3.5 Specific methodology for the study of patient organisations

Besides the work on the reviewed AFs and their domains and criteria, a research process was also applied to get insights from patient organisations in Europe regarding the quality of apps.

For this work, a qualitative approach was applied to gather valuable inputs from respondents. An initial background analysis was made with a search on the Internet using the terms "patient organisations", "health apps", "reliability" and "validity" to identify organisations that had made a position towards health apps or had public resources available about digital experiences and located in Europe.

A convenient sample of 7 organisations, four national and three European, was selected to increase the probability of response rate in the available time frame. The organisations were contacted via e-mail, which contained information about the European mHealth Hub project and a request for digital/e-mail interview about health apps' experience. Four organisations responded and made appointments for digital interviews and one organisation communicated by e-mail. Seven organisations have been approached and five were successfully interviewed. The case studies were enriched with a sixth experience based on desk research, about a position paper from IDF Europe.

The goals of the digital/e-mail interview were to collect information about how patient organisations experience health apps, the position towards validity and reliability, their experiences with initiatives, national and European trends and models in the health apps' area, awareness of application frameworks, patients' (members) needs and digitalisation.

The interviews were conducted by researchers within the health informatics field during May and June 2020. The interviews had a duration of 30-45 minutes and made on the digital platform MS Teams v1.3.

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4. Results

4.1 Evaluation domains and criteria for health apps

Overview of results on domains and criteria

The domain of **Privacy** was addressed in almost all AFs. This observation can be viewed as a successful effort of law and policymakers, focused to ensure the privacy of the personal data. Consent of the user with the data collected by the mHealth solution is put to the forefront. However, the frameworks often address privacy as a whole and do not differentiate whether the personal health data is protected from unauthorized access (e.g., loss, theft) or misuse and secured against breaches.

The reviewed AFs often explicitly address **Transparency**, similarly to the domain of Security. Transparency focuses on whether the user is informed about what information they are giving to the application. Additionally, the process of how the information is used and managed is considered as a relevant transparency issue. The transparency of algorithms that are used to analyse the data is often not considered or explained in enough detail to be understood by a layperson.

Reliability assessment is not much present on the frameworks analysed. The analysis on the Reliability evidenced that a little is evaluated in terms of data handling and results consistency.

Where present, **Validity** assessment is concentrated on literature backed content and validation from health professionals.

The **Interoperability** of the health apps can be regarded as a key aspect essential for their rapid deployment and integration into existing healthcare systems. The majority of the reviewed AFs does not cover the domain of interoperability at all. However, a growing number of the AFs identified the importance of interoperability and some address the domain in great depth. Taking the six interoperability layers into consideration, defined by the New European Interoperability Framework , only singular components of interoperability are drawn into focus by the AFs and by the mHealth solutions in the first place.

In a general way, domains such as **Safety** and **Security** were moderately existent across the board. These important domains reflect the concern that AF owners have. **Safety** is not always addressed as having a clinical bias, but rather a security one. Security most of the time overlaps with privacy concerns and few frameworks address the technical side of security, such as network security, for example.

The domain of **Technical Stability** is partly addressed in the reviewed frameworks through other criteria such as technology criteria, technical design, security, data privacy, and usability. Partly addressed means that criterion, which requires for application to maintain a level of

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performance, is covered in less than 50% of reviewed frameworks. Therefore, this report would like to draw attention to the importance of this criterion in mobile health applications.

Effectiveness criteria is of the utmost importance for assessing the product (application) itself. For approving a health mobile application, it is inevitable to point out and review the risks and side effects that can be caused using the application. Equally important, it is important to check what are the claimed health benefits of the application and is there any evidence of those. Even though effectiveness is addressed explicitly in only 9 of 24 AFs with dedicated section or at least one compliance question, only four AFs fully cover effectiveness domain (all the criteria considered within the domain). Finally, more explicit reference to key **ethical concepts** should be included in the design of mHealth apps. It has been observed that ethical issues are not always directly addressed or labelled as ethical issues in the AFs, but often contained within other criteria.

Scaling-up is not so much addressed and usually it assesses the interconnection with different platforms and interoperability between health systems. There is a clear gap in this subject due to different operating systems for the same solutions and if these differences do comply with all the regulations or if the quality standards remain.

In a broad overview of the work developed, several AFs were shy on having every category defined for **Safety, Reliability, Validity** or **Security**. More so, as a set of criteria under each domain was created, less and less alignment with these criteria was found. One can say that some expectations on what was needed to find were not met. This situation allows for some reflection on what is needed to be addressed in this field.

Approximately half of the AFs addressed **Accessibility**. Some of them at a very overall/superficial level and others indirectly by questioning if the app is suitable for the user group. Several of the frameworks provide links to relevant laws and standards for accessibility.

Approximately half of the AFs addressed **User Experience and/or Usability**. Some of them were presented in a detailed way with usability criteria and metrics, others at quite general level and not stating what factors were considered. Several of the application frameworks mention ISO-standards and certification.

With regard to evaluation domains and criteria, Annex 4 includes several visualizations about the coverage of the different criteria under each domain.

4.1.1 PRIVACY

- *[1] Domains of privacy and security are in many cases not addressed separately but rather jointly.*

The domains of privacy and security are interconnected. A clear distinction, however, can be made between compliance with the applicable laws and guidelines and security measures taken

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to protect patient data. Frameworks directing each domain separately, address on average the two domains in more depth.

- *[2] Differentiation between protection of personal data from unauthorized access (e.g., loss, theft) or misuse and secured against breaches is often not made.*

The privacy aspect of personal data is often addressed only superficially. Specific privacy concern regarding unauthorized access (e.g., loss, theft) or misuse of personal data are often not distinguished or explained in enough detail to also be understood by a layperson.

- *[3] The consent of the user with the data collected by the mHealth solution is put to the forefront.*

In recent years, there is a fundamental shift towards a "consent of a user", driven by legal actions such as the General Data Protection Regulation enforced by the European Union. Less attention is given on how the personal data are managed in terms of access, retention policy and transmission methods.

- *[4] Most of the frameworks don't address the use of analytics*

Many mHealth applications can be used free of charge. However, growing concerns accompany tracking of users by collecting data about their behaviour (e.g., interaction with the app, frequency of use). A data-driven decision about e.g., advertisement is subsequently done. Collected data can be also provided to third-party rising data protection concerns. Information about how and to what extent analytics can be used is addressed only by some frameworks.

4.1.2 TRANSPARENCY

- *[1] The focus of the assessment in the domain of transparency is put on the fact whether the user is informed about what information they are giving to the app, and how the information is used and managed.*

The reviewed AFs provide information about what user's data are being collected and how they are used and managed by the health app. Informing the user/patient about the data use is also linked to privacy aspects since only relevant information that is needed to fulfil the application's functionality in terms of treating/monitoring/informing the patient/user should be collected by the health app.

- *[2] Distinction between who is distributing, financing, and developing the mHealth app creator/owner is often not assessed/captured by the frameworks.*

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The creator/owner of the health app is usually considered in the AFs. The transparency could be increased by addressing who is distributing, financing, and developing the app. The differentiation between these two groups would allow an easier evaluation of potential interests and therefore increase transparency.

- *[3] Users are often not informed about algorithms and underlying datasets used to analyse their data.*

From a patient's or user's point of view, it is often hard to get information about the used algorithms within an app nor on the data that is used in these algorithms. The analysed frameworks do not sufficiently cover this shortcoming since the frameworks do not state best practices or rules on which basis a health app can be evaluated. The question of algorithmic transparency arises and lets a layperson (as a typical user) staying uninformed.

4.1.3 SAFETY

- [1] *Often there is a general assessment of safety but not much detail is given.*

In most AFs the word "safety" is sometimes used interchangeably with "security". This report made a clear differentiation between the definition of "safety" and "security"[27] and with this we are able to define two different concepts for a more complete assessment. Safety is a major concern when it comes to dealing with people's health and a must when assessing apps related to health, but some frameworks don't have one clear reference to this domain.

- [2]. *Every criterion under Safety domain was, at least once, present on the frameworks assessed.*

The criteria defined for the Safety domain were addressed at some extent by most of the AFs. This confirms that the criteria were pertinent for assessing Safety, and it paves the way to more concrete recommendations and a good evidence for a holistic approach on this domain.

[27] Safety: ensuring the mHealth solution does not cause any harm to the users, be it of physical, mental, social or financial nature. Security: the framework considers whether personal health data is stored, transferred, and managed securely (i.e. the app uses up-to-date security standards). The framework confirms that the app does not require more information than needed for the purpose of the app. (See Table with the Domains definitions).

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- [3] *National and regional frameworks address more criteria for the Safety domain than international ones.*

National AFs tend to have more correspondence to the Safety domain and the criteria defined. This doesn't mean that Safety is not an important issue in international frameworks but rather that the criteria defined for the purpose of this work is more aligned with the national or regional AFs. These AFs tend to be closer to the citizen and thus being possibly a catalyst for having a closer approach and concern for the safety of the citizens. The major difference here in terms of criteria is assessing that the app poses clinical risk and assessing the quality and validity of the clinical information of the apps.

- [4] *User input validation was the least reported criterion and the most reported one was content quality in terms of clinical validity.*

User generated data is still in a development state, this is due to the crescent penetration of apps that collect data from citizens from wearables and other devices, such as digital scales. Because of that, user input validation is a growing concern and one focus of the work presented here. The criterion that addresses this subject[28] was the least seen in the research made. On the other hand, a closer attention is paid to content quality and validity. This is one of the main pillars of the Safety domain in study here.

4.1.4 RELIABILITY

- [1] *Most frameworks don't consider reliability analysis/assessment.*

Reliability appears to be less explored and assessed on the frameworks studied than expected. Reliability is a measure of reproducibility and consistency of a health app and for that an assurance of consistency of results and applications to the citizens. Consistency in apps that manage chronic diseases, for example, can have an impact on safety as well. Lack of reliability can pose a risk to certain users and a concern that interlinks with other domains. On the other hand, the frameworks that assess Reliability, tend to analyse effectively its consistency through evaluation that the app consistently gives the same results given the same set of parameters as input.

- [2] *Specific reliability assessment tools are overlooked across the board.*

For statistical applications and handling of data it is a good practice to use reliability tools and methods. One of the general classes of reliability estimates is inter-rater reliability. This class of

[28] 6."Explicitly evaluates user input validation (this can include external hardware validation)".

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reliability estimates is used to assess the degree to which different evaluators/observers give consistent estimates of the same phenomenon[29]. From that definition we can make the case that for health apps, the data processed need to produce consistent outputs from the same inputs, or phenomenon. On the AFs analysed none had this method/tool as an assessment question. Normally this can link to the fact that inter-rater reliability is a very specific tool to be massively adopted. The same is true for the test-retest reliability. The lack of assessment of these tools is seen as an opportunity to expand the AF.

- [3] *Some frameworks use the term "reliability" without referring to the criteria defined.*

The domain Reliability does not have a significant focus in the frameworks assessed when talking about the criteria selected. This fact deserves a closer look on the criteria defined and opens the opportunity of possible future adaptation for other criteria.

4.1.5 VALIDITY

- [1] *Validity is only addressed in half of the frameworks.*

Validity in terms of definition on the frameworks assessed have a very coherent definition and connection to clinical validity and the validity of the information present on the application reviewed by experts, health professionals and authorities. Half of the frameworks address validity explicitly and because of that there is room for improvement on this domain. Health data which serves as a basis for the mHealth solution must be checked and validated, otherwise is easy to see the implication for safety of the user. Validity also leads to consistency and reliability of the data presented to the user, benefiting the developers and the user itself for a quality product in accordance with the standards and the latest scientific information available.

- [2] *Where validity is assessed, the focus is whether the information is backed by health professionals/clinicians/health authorities, and in validation from literature.*

The previous point focused on the state of validity assessment; this paragraph focuses on the frameworks that assess validity. As a good example the French High Health Authority Assessment framework (Good practice guidelines on health apps and smart devices)[30] that not only assesses the design of initial content within regulations from national guidelines and good practices but also assesses that the mHealth solution has a procedure for updating its information during the solution lifecycle. Also, in this framework there is a clear overlap of this

[29] https://conjointly.com/kb/types-of-reliability/

[30] https://www.has-sante.fr/upload/docs/application/pdf/2017-03/dir1/good_practice_guidelines_on_health_apps_and_smart_devices_mobile_health_or_mhealth.pdf

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domain with other ones such as Reliability. Other good examples that can be referred are UK's NHS DAQ[31] and Germany's BfARM[32] which have a comprehensive look at how the information is included in the mHealth solutions.

- [3] *Comparisons with control groups and validation of information from external hardware/equipment are less assessed.*

Control groups and trials as a validation of health/clinical information is one of the ways to achieve validation. This can be important on applications for chronic diseases, for example. More so, traditional regulatory models have an important role in making certain apps available for clinical care, and it is anticipated that these regulated apps will also have evidence supporting their use, such as a randomized control trial[33]. Such connection makes it important to assess this comparison and inclusion of control groups in validating clinical information.

The growing adoption and use of wearables, as referred before, creates a concern on the data collected and consequently the quality of it and the real use for it. Validity must not be only assessed on the developer/service provider side, user generated health data must also be considered and validated. On most AFs, in data gathered by external sources (hardware/equipment), the concern on user generated data does not have an explicit focus and attention. Patient generated data is considered of lower quality than clinical data and hence the reluctance to integrate it with clinical data. So, if a health app has a good reliability and validity, it inspires confidence to be integrated in health systems smoothly.

4.1.6 INTEROPERABILITY

- *[1] The majority of the reviewed assessment frameworks does not cover the domain of interoperability at all.*

The interoperability of the health apps can be regarded as a key aspect essential for their rapid deployment and integration into the healthcare system. Assessing the achieved level of interoperability (i.e., 1. foundational, 2. structural, 3. semantic, or 4. organizational) would further support this process. More detailed information about the applied layers of interoperability would also help to assess the potential integration into regional or national frameworks.

[31] https://digital.nhs.uk/services/nhs-apps-library/guidance-for-health-app-developers-commissioners-and-assessors/how-we-assess-health-apps-and-digital-tools#step-3-technical-assessment-and-standards

[32] https://www.bfarm.de/EN/MedicalDevices/DiGA/_node.html

[33] https://www.nature.com/articles/s41746-019-0212-z

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- *[2] The data formats (e.g., standards like XML, or JSON) used for import/export and transmission to different information systems (e.g., EHR) and interpretability of sent/received data is often not addressed.*

The used data formats influence the integration of the mHealth application to different information systems. Additionally, they are linked to the interpretability of data from both computer and human perspective based on used terminology and included contextual information. Information about the layers of semantic and technical interoperability would help to allow better integration of health apps and would lead to higher transparency as a side-effect.

- *[3] Open transparent and harmonised standards for data sharing is often not addressed, Additionally, sematic interoperability in terms of use of standardized vocabularies, code lists, and terminologies is not considered.*

Considerations of harmonised standards used are consequential for data sharing capabilities of an mHealth solution. As well as the concrete specification of the semantic interoperability in terms of use of standardized vocabularies, code lists, and terminologies is not provided by the majority of investigated frameworks.

4.1.7 TECHNICAL STABILITY

- *[1] It is important that the assessed application can maintain its level of performance and have consistent technical functionality.*

The definition of the technical stability domain was taken from 2018 report[34]: "*The framework considers the app's ability to maintain its level of performance under stated conditions for a stated period of time. Consistent technical functionality may be supported by provisions such as a regularly updated FAQ for users or regular monitoring of software for bugs. Note: overlaps with reliability*".

Of the 24 assessed frameworks, only 8 explicitly addressed technical stability with dedicated section or at least one compliance question. To assess whether a framework includes technical

[34] Report on the mHealth Assessment Frameworks, May 2018. Contributors: Meghan Bradway, Eirik Arsand, Konstantinos Antypas, Per Hasvold, Jennifer Lee, Natalia Wroblewska.

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stability domain, as many as 9 criteria are specified[35]. None of the assessed frameworks fully covers technical stability domain.

- *[2] To ensure that the app can maintain its level of performance, it is important to do testing in the conditions of the sudden increase in the number of users and the sudden increase in the amount of data (load test, stress test).*

Most of the assessed frameworks do not mention "technical" application testing. The main question about testing, asked in the AFs is "*Do you do any testing?*", and it is usually followed by "*Are end users included in testing*?", which covers more usability than technical stability.

- *[3] The most covered technical stability criterion is covered in less than 50% of assessed frameworks.*

The most covered criterion through the analysed AFs is whether the application can work in the offline mode. Still, only 13 out of 24 reviewed frameworks covered it.

- *[4] Regular application monitoring, tracking the number of app crashes and uptime, and updating FAQ regularly should all be standard and mandatory.*

Only 8 of 24 assessed frameworks check if application is regularly monitored, if there is track of the number of app crashes and uptime, and if FAQ is updated regularly.

- *[5] Technical stability is partly covered in other criteria such as technology criteria, technical design, even security, data privacy, and usability.*

The criterion "*Sensitive data is not exposed, and security is not compromised if application crashes (due to any reason)*" is covered as a part of security criteria or data privacy in some frameworks.

Some of the AFs that do not explicitly address technical stability, address technology criteria, or technical design. Most common questions asked are related to which platforms the application is available on; if the user can ask a question and report a bug in the application, and whether the user is informed about the application upgrade.

[35] Table **3**. Evaluation domains and criteria

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4.1.8 EFFECTIVENESS

- *[1] Effectiveness is of the utmost importance for assessing the product (app) itself.*

Whether the framework covers effectiveness is addressed according to definition from 2018 report[36]: "*The framework considers whether the app is evaluated against any claimed health benefit or improved health outcome. Does the app fulfil its intended function for the user? Factors contributing to effectiveness include:*

- *Evidence of clinical benefits and cost-effectiveness of its mHealth solution (i.e., peer-reviewed studies and trials);*
- *A measure of desired or intended result in every-day use and particular environments;*
- *The capacity to reach the target population with minimum resources invested to improve general health of the population*".

Taking this definition as reference, a discussion was developed in the research team about which of the effectiveness/efficacy/efficiency the AF should assess. The conclusion of the working group was that effectiveness is of the utmost importance for assessing the product (application) itself. Although effectiveness is being assessed through AFs, it is recorded if efficacy or efficiency is explicitly addressed in the analysed framework.

To assess whether a framework includes effectiveness domain, 7 criteria are specified[37]. Even though effectiveness is addressed explicitly in only 9 out of 24 AFs with dedicated section or at least one compliance question, criteria are addressed in more than 50% of reviewed frameworks. Four AFs fully cover effectiveness domain covering all specified criteria, including explicitly addressing effectiveness. Those four are: Evidence Standards Framework for Digital Health Technologies[38], AppKRI[39], AppQ[40], and BfArM's DiGA-Fast-Track and Guidance

[36] *Report on the mHealth Assessment Frameworks,* May 2018. Contributors: Meghan Bradway, Eirik Arsand, Konstantinos Antypas, Per Hasvold, Jennifer Lee, Natalia Wroblewska. (21 pages)

[37] Table 3. Evaluation domains and criteria

[38] https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies

[39] https://ehealth-services.fokus.fraunhofer.de/BMG-APPS/

[40] https://blog.der-digitale-patient.de/appq-veroeffentlicht/

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Document [41]. AFs ISO/TS 82304-2[42] and PAS 277:2015[43] do not explicitly address effectiveness but they cover other 6 of specified criteria under the effectiveness domain.

- *[2] Most of the frameworks check whether the application is evaluated against any claimed health benefit or improved health outcome.*

More than 80% of reviewed frameworks (20 out of 24 AFs) can capture in some way what health benefits the app is claiming to have and if evidence about the claimed benefits is available. Different levels of evidence (e.g., expert opinion, observational study, randomized controlled trial (RCT), systematic review of RCT's) can be captured in some way in more than 60% of the reviewed frameworks (15 out of 24 AFs).

Although the definition of effectiveness criteria emphasizes health benefits, it might be also important to look for other types of benefits when assessing health applications.

A good example of establishing clinical, economic or behavioural benefits of the product is described in the Technical Assessment questionnaire which is a part of Digital Assessment Questions (DAQ) by NHS Digital[44]. For three types of benefits (clinical, economic and behavioural), it is asked if the product has any benefits, if evidence of claimed benefit exist, and what type of evidence it is. Regarding clinical benefits, one example from this AF is: "Are there any clinical benefits to using your product? For example, will it improve symptom control or clinical outcomes?"

- Describe clinical benefits and the timeframe for success.
- Do you have any evidence to show success of the clinical benefits? For example, published articles, pilot studies or user research.
- Select all relevant evidence type(s) from the following sources:
- Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" | Case series (and poor-quality cohort and case-control studies) | Individual case-control study | Systematic review (with homogeneity) of case-control studies | "Outcomes" Research; ecological studies | Individual cohort study or low quality randomized controlled trials (e.g. <80% follow-up) | Systematic reviews (with

[41] https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Beratungsverfahren/DiGA-Leitfaden.pdf?__blob=publicationFile&v=4

[42] https://www.nen.nl/Standardization/Health-and-wellness-apps.htm

[43] PAS 277:2015 Health and wellness apps. Quality criteria across the life cycle. Code of practice, Published: April 2015

[44] https://digital.nhs.uk/services/nhs-apps-library/guidance-for-health-app-developers-commissioners-and-assessors/how-we-assess-health-apps-and-digital-tools

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homogeneity) of cohort studies |All or none randomized controlled trials | Individual randomized controlled trials (with narrow confidence interval) | Systematic reviews (with homogeneity) of randomized controlled trials

- Upload a relevant document or provide relevant URLs.

- *[3] It is important to point out the risks and side effects that can be caused using the application.*

14 out of 24 reviewed frameworks can capture health risks and side effects that can be caused using the application. Even though the percentage is slightly higher than 50%, it is still a bit worrying that the percentage is not higher, given the importance of this criterion for user safety. When pointed out in the AFs, capturing risks and side effects is usually not part of the effectiveness criteria. It can be found more often under patient safety, clinical safety, device safety, quality, and risks.

- *[4] It is important to measure whether the desired or intended result of the application usage has been achieved (e.g., improved health outcome).*

The least covered criterion in the AFs is measuring the desired or intended result (e.g., improved health outcome) which could be very important to prove the effectiveness and usefulness of the application.

- *[5] Ethical issues are not always directly addressed or labelled as ethical issues in the AFs*

As a part of the effectiveness, the criteria "*framework can capture the app's applicability by distinguishing different subgroups (e.g., gender, age, health literacy)*" was added. After going through 24 frameworks and studying how different frameworks met the criteria, it is quite clear that the app's applicability for different subgroups is covered under domains such as accessibility, usability, appropriateness, and user experience.

While assessing criteria about distinguishing subgroups of users due to demographics, age, gender, health literacy, medical condition, health status, it has been observed that ethical issues are not always directly addressed or labelled as ethical issues in the AFs, but often contained within other criteria. For example, transparency is an ethical as well as practical issue.

4.1.9 ACCESSIBILITY

- *[1] Different levels of depth in addressing accessibility.*

There are frameworks that have an entire category or chapter on "accessibility", others mentioned or consider it as a sub-category, and other frameworks omit the word "accessibility"

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but e.g., mention "access" to data and information, "inclusivity", or "reliability". Several frameworks do not mention accessibility directly.

In some cases, the responsibility for accessibility is deflected onto the designers: "designers should ensure their products are accessible". Some frameworks offer limited accessibility as they are not translated into English. (e.g., the German word for accessibility is "*Barrierefreiheit*").

- *[2] Only a few frameworks mention reasons or specific aspects of accessibility.*

The analysis regarding accessibility criteria within frameworks found that only a few AFs take varying user groups' needs into account. This means that only a few AFs address accessibility for special needs user groups specifically.

In some cases, accessibility was referred to as the designer responsibility, without mentioning clearly, which criteria should be regarded to ensure accessibility for specific user groups. An example would be: "The designer sets up a specific user test for disabled users".

Some AFs refer to the necessity to offer additional help during the usage of apps: "support for user groups with difficulties/impairments" must be offered. This approach does not ensure a better accessibility through design, but through additional support.

In Germany, for an app, to be listed in the DiGA "digital health app" (and therefore is listed as an app supported by health insurance), it must comply with the requirements set in the *Bundesgesetzblatt*[45] part 18 nr. 1 "Usability and Accessibility" (3. § 5 *Absatz* 6). This means that "by 1 January 2021 at the latest, the digital health application will provide assistive devices for people with disabilities or support the assistive devices offered by the platform".

- *[3] Frameworks mostly refer to "universal design guidelines", to standards provided by the International Organization for Standardization, or they mention that techniques to ensure accessibility should be used. However, the frameworks often fail to mention concrete design or evaluation criteria.*

The concrete accessibility criterium "Text and image readability" was mentioned in direct relation to user abilities within a few frameworks. Similar to how some frameworks are referring to design guidelines and standards for details, another example is a framework referring to a

[45] http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl120s0768.pdf, Bundesgesetzblatt Teil I Nr. 18, Verordnung über das Verfahren und die Anforderungen zur Prüfung der Erstattungsfähigkeit digitaler Gesundheitsanwendungen in der gesetzlichen Krankenversicherung (Digitale Gesundheitsanwendungen-Verordnung - DiGAV, 8. April 2020)

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specific framework for accessibility (from a different source), and therefore outsourcing information about accessibility criteria.

- *[4] Transparency, in the sense of making transparent the existence of limitations for accessibility, is covered in several frameworks.*

The accessibility criterium of disclosed "transparency" is often mentioned in a rather generic way, such as: "*Is this information accessible for users to consult?*". In other cases, frameworks clearly state that transparency should be regarded, however, similarly to the previous criterium (accessibility for special user groups), frameworks often do not go into detail about how transparency should be disclosed and what should be mentioned specifically. Some frameworks indicate that the scope of the app should be clearly defined, outlining the importance of explaining contraindications, potential risks and limitations of use, and including examples.

- *[5] Standards/guidelines for usable development (which indirectly include those with disabilities or limited cognitive ability, as usable development is targeted to understand user needs of all stakeholder groups) are frequently referred in the frameworks. However, only a limited number of frameworks refer to the specific criteria for accessibility. In addition, many frameworks, standards and guidelines refer to data accessibility or safety and security rather than accessibility in terms of interface design or varying abilities or literacy among user groups.*

In some specific cases, the aspect of transparency is covered through explaining that apps have to comply with the legal and technical requirement or guidelines set out in the applicable App Store.

Overall, it was noticed an **underrepresentation of explicitly addressed accessibility** concerns in most of the frameworks. They were often grouped under the umbrella terms "Usability" or "User Experience". "Accessibility" was in many frameworks described as a sub criterion of these. Therefore, the criterion "Accessibility is explicitly addressed in the framework" was often met under bare minimum standards. When accessibility had more than one concrete mention or had a dedicated sub-criterion within the framework, the overall mentioned criteria were "fulfilled", and the finding was described in this report. In several cases, the framework only mentioned "access" and referred to development principals or guidelines for design[46].

[46] Example: "[...] *is doing its best effort to ensure the total access to the information available in its website. Thus, the Recommendations for Mobile Health Apps Users' rights: website accomplishes the World Wide Consortium standards (W3C) in level A. Recommendation 2: Health App should be based on Principles of Universal Design*" (Andalusian framework, Safety and Quality Strategy in Mobile Health Apps).

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The understanding of the term "accessibility" varied across frameworks. Within many frameworks, accessibility was described as concerning data or information access on a technical level as opposed to including and trying to meet a variation of user needs. Therefore, the criteria about whether users and their abilities are included, often fell short.

Techniques or concrete details to ensure accessibility mentioned in the frameworks were limited. Text or image readability and size were mentioned, but beyond general design guidelines, not many recommendations or further input was found. Only one framework[47] mentioned a standard for accessibility explicitly.

A framework for accessibility is explicitly mentioned in one framework[48], even though accessibility is seen as a merged topic with usability: "*All products are assessed against Web Content Accessibility Guidelines 2.1, which are the agreed international standards for digital accessibility that all web content must satisfy. This: - is to make sure that products provide access to as many people as possible, including older users, younger users and those with disabilities; - might involve being able to increase text size where needed and work with voice software to help people with visual impairment*".

Even in this example, the questions regarding ensuring accessibility are very limited. Further input, examples or guidelines would be of value to ensure accessibility in a health-related context of use. It seems like an extensive analysis of the context of use and the inclusion of a multitude of users, has not yet bridged into common understanding of the design for such apps. In health environments, it is especially important to adequately include all potential target users.

Transparency, or **"the scope of the app" is mentioned in many frameworks on a general level** and not necessarily on the accessibility level. However, there is a common understanding that transparency is very important and that the information about the scope/transparency needs to be accessible. The assumption could be made that when accessibility is regarded in more detail within frameworks, the mentioning of more detailed accessibility transparency would also increase.

In general, **national, EU and international laws, web accessibility guidelines and standards are mentioned very frequently**. However, these criteria suffer the same lack of details for accessibility as the one about "transparency". Mentioned laws, guidelines, frameworks are usually about design standards or data handling (sometimes specifically within

[47] *Digital Assessment Questions (DAQ) – NHS Digital*

[48] *Digital Assessment Questions (DAQ) – NHS Digital:* https://digital.nhs.uk/services/nhs-apps-library/guidance-for-health-app-developers-commissioners-and-assessors/how-we-assess-health-apps-and-digital-tools

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a medical environment). **Concrete standards for those with disabilities or limited cognitive ability (visual, hearing, impaired speech) are not mentioned.**

4.1.10 SCALABILITY

- [1] *This domain is the least observed.*

Scalability as assessment domain has a focus on the potential and steps taken by a mHealth app to expand its market or user base. This includes new platforms, new geographies and cultures. With that consideration as a relevant aspect of this analysis, few frameworks have an explicit concern about such topics, with more cases of this issue being assessed in worldwide used frameworks. global embrace, are more likely to assess the scalability procedures of the mHealth solutions.

- [2] *The focus on this subject is connection and interaction with other services and devices.*

Despite the main focus, Scalability domain is not all about expansion, is also about the new platforms. These platforms might be an update of an old platform in use and an upgrade on certain infrastructure, which the mHealth solutions need to connect to and exchange information/health data with. Given the importance of this information, it is crucial that health apps can handle these changes and continue to protect citizens' health data as personal information. Those AFs that assess scaling up have this focus.

4.1.11 USER EXPERIENCE AND USABILITY

- [1] Different levels of details in addressing usability.

Approximately half of the reviewed AFs addressed **user experience and/or usability**. Several of them were presented in a detailed way with a subset of usability criteria and metrics. Figure 2 shows 4 out of 44 criteria for the evaluation of usability of health apps by one of the assessment frameworks analysed[49]. This framework had several of the most detailed set of criteria and they were publicly available on the webpage, but it focused mainly on user interface and technical issues and has less emphasis on the user experience. User experience has a wider

[49] https://ticsalutsocial.cat/wp-content/uploads/2018/08/acreditation-criteria.pdf

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perspective and involves users in the testing, whereas usability has a more technical focus on the user interface and can be made by experts. The information compiled in one of the drafts (2016)[50] for the work of the EC Working Group on mHealth assessment guidelines constituted also a relevant effort, including detailed usability metrics with 28 questions targeting assessment of how usable and accessible the application is.

Usability

	Criteria	Level 1	Level 2	Level 3
U.01	**The main elements (text, images, icons, buttons, etc.) are identifiable and easy to use** The visual elements have a size and an optimal resolution allowing its identification.	Recommended	Compulsory	Compulsory
U.02	**The registry form is quickly for filling (it does not contain more than five fields)** The App registry form has the necessary fields, and it can be answered quickly, it can be done without the need of seeking further information.	Recommended	Recommended	Recommended
U.03	**The text font is understandable and easy to read (size, color, and font)** The type of text font has a size and color enabling its easy reading.	Recommended	Compulsory	Compulsory
U.04	**There are options to sound alerts: visuals or by vibrating** The App offers alternative preferences to the sound alerts to easy its accessibility as visual alerts or by vibration.	Recommended	Recommended	Compulsory

Figure 2 Examples of usability criteria for accreditation (Tic Salut Social)

- *[2] Human factors in user experience*

Several frameworks addressed **related standards** in their assessment. The ISO 9241-210 standard for human-centred design is mentioned in the technical assessment document from *DAQ (NHS Digital)*[51], stating the phases of human-centred design, end-user demographics, user research on user needs, number of tests with users and how, and changes in light of user feedback both pre-and post-release. The usability standard ISO 9241-11 and ISO 62366 are mentioned in the work developed by the *EC Working Group on mHealth Assessment guidelines*. The medical device standard BS EN 62366-1 and the FDA's usability guidance are mentioned in *PAS 277:2015. mHealthBelgium* focuses mainly on CE-marked devices[52], however, their target users are listed.

[50] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20160607_co06_04_en.pdf

[51] https://digital.nhs.uk/binaries/content/assets/website-assets/services/nhs-apps-library/daq.pdf

[52] https://mhealthbelgium.be/

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Co-creation is addressed in several of the frameworks. For example, the ISO/TS 82304-2 states "*co-creation in which a representative sample of intended users were engaged to establish an adequate understanding of health requirements, contexts and current health interventions*". The *Evidence Standards Framework for Digital Health Technologies* also addressed representation from intended user groups in the design, development or testing[53]. Some other AFs also addressed user engagement and its evaluation.

- *[3] Consideration of the user context*

Regarding if the app considers the user, the system and the context of use, there is one example[54] that addressed measurement performance in the environment of use by asking: "*Is measurement performance documented in the environment or context of use (contextual robustness) and is it justified by the intended use of the product*?", with the justification that a measurement taken in a real-life situation may differ from measurements taken in the laboratory. Further, this framework focused on user-friendliness and intuitiveness of the interface and navigation, by addressing tests with different user profiles and documentation of testing plan and reports. In *Our Mobile Health* framework, it is also mentioned the context of real patient testing at home.

- *[4] Suggested methods for user experience testing.*

The fourth criteria analysed under this domain addressed user experience testing (prior to the market release) and this was stated in a few frameworks, for instance in *PAS 277:2015* by proposing that requirements should be tested as early as possible in the development and including the following methods: review, interviews, wireframes and field testing. Other frameworks as *AppKRI* also suggests actions as pilot study or field test to be made; user-friendliness of the graphical user interface (*GGD App Store*).

Other frameworks addressed assessment of products against an industry-validated usability assessment tool, using participants who are demographically similar to intended users (target audience) (*cmHAFF*)[55], what is congruent with the consideration of user demographics (e.g., *NHS DAQ*). *cmHAFF* addressed testing based on a written usability assessment plan, including

[53] https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf (page 14)

[54] https://www.has-sante.fr/upload/docs/application/pdf/2017-03/dir1/good_practice_guidelines_on_health_apps_and_smart_devices_mobile_health_or_mhealth.pdf

[55] http://www.hl7.org/index.cfm

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known problems with product usability, specifically addressing usability issues for people with visual and motor disabilities.

- *[5] The user interface experience.*

Regarding the criteria about user interface experience, technical interface guidelines were covered in some frameworks (interface meaning mainly about data exchange, not related to human interactions), like *Continua Design Guidelines (CDG)*. The Technical platform was also addressed in some frameworks, like *ORCHA or the past EC Working Group on mHealth assessment guidelines*.

Usability is assessed in several frameworks based on self-declaration, such as eHealth Suisse presenting nine criteria for better transparency in health apps[56].

There were differences between the frameworks regarding user experience and usability. Several frameworks did not explicitly mention user experience and usability, while others mentioned them, but with limited criteria or referring to usability in general terms. Only a few frameworks had detailed usability metrics that were publicly available.

4.1.12 SECURITY

- [1] *On the analysed frameworks, the focus of security usually lies on privacy.*

Security has a great focus on the data and protection of information of the user. It is natural to have some overlaps with privacy. Exchange of health and private information is a major concern in the world we leave in. Major data security measures are in place in most of the devices that we use on a daily basis, so it is natural to have this concern mirrored explicitly in most of the frameworks. Building up on what is described in the previous sentences, there is a focus of the security chapters on the transfer and communication of sensitive information whether from device to device, or from device to third parties.

- [2] *Fewer frameworks evaluate the technical side of security.*

On the side of the technical security, fewer frameworks focus explicitly on this matter. The gap that was verified represents also a missed opportunity on having this important aspect

[56] https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/D/kriterienkatalog-selbstdeklaration-gesundheits-apps.pdf

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assessed. In our world, network security, communication protocols, are already being massively used. App development guidelines and most of IDE tools (Integrated Development Environment) already have this concern and facilitate developers on paying attention to these subjects. With development technology and national regulations already very focused on technical security, it is only expected that this focus became rapidly included in the AFs. One last note is that some specifics about cryptographic security go beyond the analysis carried out in this criteria coverage. The analysis carried out intended to be more extensive and less intensive.

4.2 Health apps repositories

So far, twenty-two repositories have been identified in **eleven different countries or regions** (Belgium, Southern Denmark, France, Germany, Netherlands, Norway, Portugal, Andalusia (Spain), Catalonia (Spain), United Kingdom (including separate example of Scotland). Most of them can be seen as the product of one of the assessment frameworks analysed in this report, and both public-led and private initiatives have relevant presence in the development of repositories. Even in some cases they come from partnerships or joint efforts between these two kinds of actors.

The whole list of repositories, the organizations behind them, the country/region and the languages in which the information is fully or partially displayed is showed in the following infographic and table. The infographic will be updated in the website and social media to include the last three repositories added (DiGA, Norway, Guide for mental health apps).

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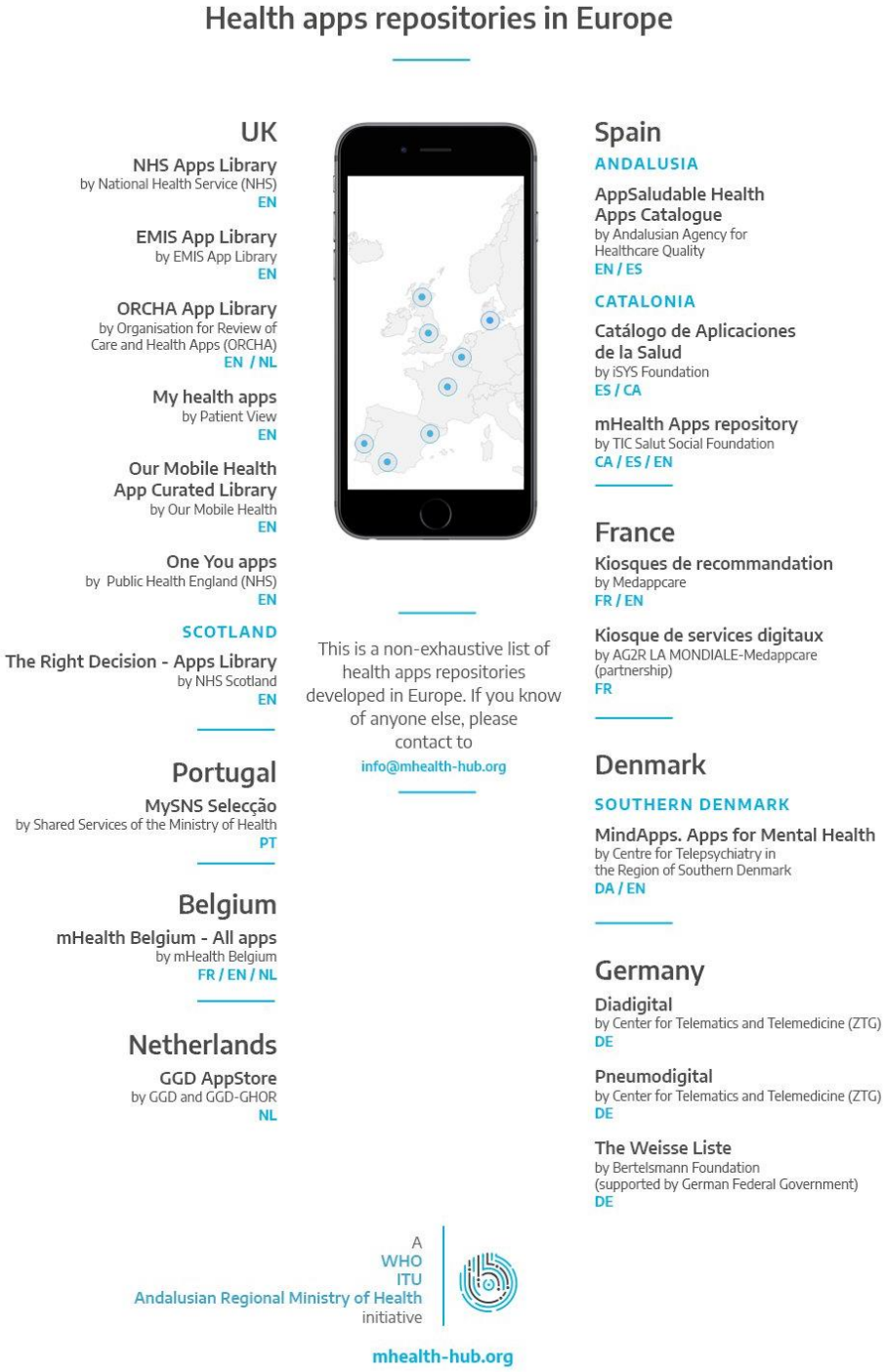

Figure 3 Infographic: health apps repositories in Europe

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Health apps repository name	Organization	Country or region	Languages available									
			EN	ES	FR	DE	NL	PT	DA	ET	NOR	Cat
mHealthBelgium - All apps	Belgian Federal Government (with other stakeholders)	Belgium										
Mind Apps: Apps for mental health	Centre for Telepsychiatry, Region of Southern Denmark	Denmark (Southern Denmark)										
Store d'applications mobiles et de sites web recommandés	DEKRA Certification	France										
Kiosque de services digitaux	AG2R LA MONDIALE – Medappcare (partnership)	France										
DiaDigital	Center for Telematics and Telemedicine (ZTG GmBH)	Germany										
PneumoDigital	Center for Telematics and Telemedicine (ZTG GmBH)	Germany										
The Weisse Liste	Bertelsmann Foundation (supported by German Federal Government)	Germany										
DiGA directory	Federal Institute for Drugs and Medical Devices (BfArM)	Germany										
GGD Appstore	GGD and GHOR (public health services)	Netherlands										
Guide for mental health apps	MIND in co-creation with 'de Nederlandse ggz'	Netherlands										
Helsenorge Verktøykatalog	Norsk Helsenett	Norway										

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MySNS Selecçao	SPMS - Shared Services of the Ministry of Health, EPE	Portugal											
AppSaludable Health Apps Catalogue	Andalusian Agency for Healthcare Quality (ACSA)	Andalusia (Spain)											
Catálogo de Aplicaciones de Salud	iSYS Foundation	Catalonia (Spain)											
mHealth Apps repository	TIC Salut Social Foundation	Catalonia (Spain)											
NHS Apps Library	National Health Service (NHS)	United Kingdom											
EMIS App Library	National Health Service (NHS); IQVIA + EMIS	United Kingdom											
ORCHA App Library	Organisation for Review of Care and Health Apps ORCHA	United Kingdom											
My health apps	Patient View	United Kingdom											
Our Mobile Health Curated App Library	Our mobile health	United Kingdom											
The Right Decision - Apps Library	NHS Scotland	Scotland (United Kingdom)											
One You apps	Public Health England (NHS)	United Kingdom											

Table 4. Health apps repositories developed in Europe

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The reviewed repositories share the general objective of health apps quality promotion, making visible in a single place the apps that have undergone some kind of review or assessment. However, from that point on, the **heterogeneity** becomes the common denominator. The research team has investigated several repositories' features, observing different patterns and approaches.

- ***Repository object:*** most of the repositories have their focus in the "apps", in a generic or thematic way (mental health, diabetes, respiratory diseases, Parkinson), with some of them explicitly considering also devices, online tools, or living aids, taking into account the CE-marking. .

- ***Language:*** this constitutes a good indicator of the openness of the repository. Only 5 out of 12 non-English speaking repositories include some information in English. The others tend to develop its work mainly for national or regional target audiences.

- ***Number of apps*** included in the repository: although it would seem easy to find this information, several repositories do not include explicitly such data. There is a big disparity in the number of apps included, with some repositories including less than 50 apps, and a few others that clearly exceed that figure.

- ***How can one app be included*** in the repository: the repositories that are based on a stablished and transparent assessment process, and also in some cases a quality seal- can be seen as having a more solid background.

- ***Apps scoring and ranking:*** in some repositories these resources are used to make the assessment information more understandable or appealing for the target audiences; however, to be truly effective, these elements need to be accompanied of enough transparency.

- ***Search browser and filters:*** some repositories have gone beyond a simple list of the apps they include, enriching it with elements such as a search browser or different filters that makes the repository tool more user-friendly, especially when the number of apps is high.

4.3 Qualitative insights about the assessment frameworks

4.3.1 GOVERNMENTAL AND NON-GOVERNMENTAL INITIATIVES

Different types of organisations contribute to the development of AFs for health apps. While governmental initiatives drove or had some role in most of the frameworks' development, both for-profit and non-for-profit non-governmental institutions have created a considerable number of AFs. Regarding governmental initiatives, both national and regional initiatives have been carried out. National initiatives have been identified in France, Germany, Portugal, UK, The

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Netherlands, and Belgium. In Spain, different regions have developed different assessment frameworks: *Tic Salut Social* for the Catalan region and *the Safety and Quality Strategy in Mobile Health Apps* in Andalusia. Standards institutions, such as The British Standards Institute, Health Level 7 (HL7), The European Committee for Standards (CEN) and The International Organization for Standardisation (ISO) are also being involved in the creation of these frameworks.

4.3.2 YEAR OF CREATION AND UPDATE FREQUENCY

The development of new frameworks was steady and constant throughout the years. The Continua Design Guidelines (CDG), secure end-to-end ICT framework created to ensure the interoperability of personal connected health and care using open standards was among the first frameworks created worldwide (2008). Starting with 2012, several European initiatives were developed, such as *Medappcare Quality Approach*, *AppCheck*, and *the Andalusian Strategy for Health Apps*. The Andalusian initiative was one of the first European initiatives to also include a quality seal. The evolution of European initiatives is described in Figure 4.

To keep AFs up to date, a revision process taking into account regulatory and legislative aspects is considered by most frameworks' owners. The update frequency varies strongly between AFs. Most of the framework owners aim to update them regularly, either on an annual basis (e.g. *IsysScore*, *Andalusian Safety and Quality Strategy in Mobile Health Apps*) or every two (e.g. *Tic Salut Social*) or three years (e.g. *ISO/TS 82304-2*).

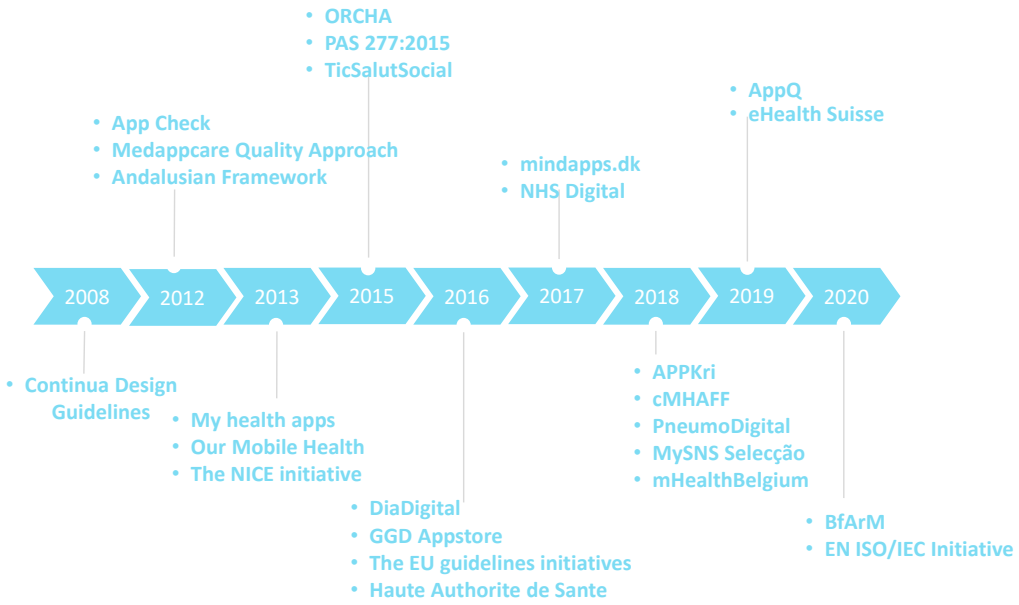

Figure 4. Timeline of assessment frameworks creation

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4.3.3 GEOGRAPHICAL APPLICATION SCOPE

Several frameworks serve international purposes, receiving world-wide applications (e.g., *ORCHA, NHS Digital, Andalusian Safety and Quality Strategy in Mobile Health Apps, Tic Salut Social, CDG, CEN-ISO, cMHAFF*). Some frameworks are limited to the state in which they have been developed or open to similar language speaking countries. For example, national initiatives have been developed in Belgium: *mHealthBelgium*, Portugal*: MySNS Selecção*, Switzerland*: eHealth Suisse* and Denmark: *MindApps.dk*. Few frameworks are not limited to the national level but are language specific initiatives. For example, *IsysScore* addresses apps from Spanish/Catalan speaking countries whereas *AppQ* focuses on Germany and German-speaking countries. The *Mindapps.dk* is anchored in the Region of Southern Denmark with a national reach. The figure found below contains the geographical coverage of AFs in the European region.

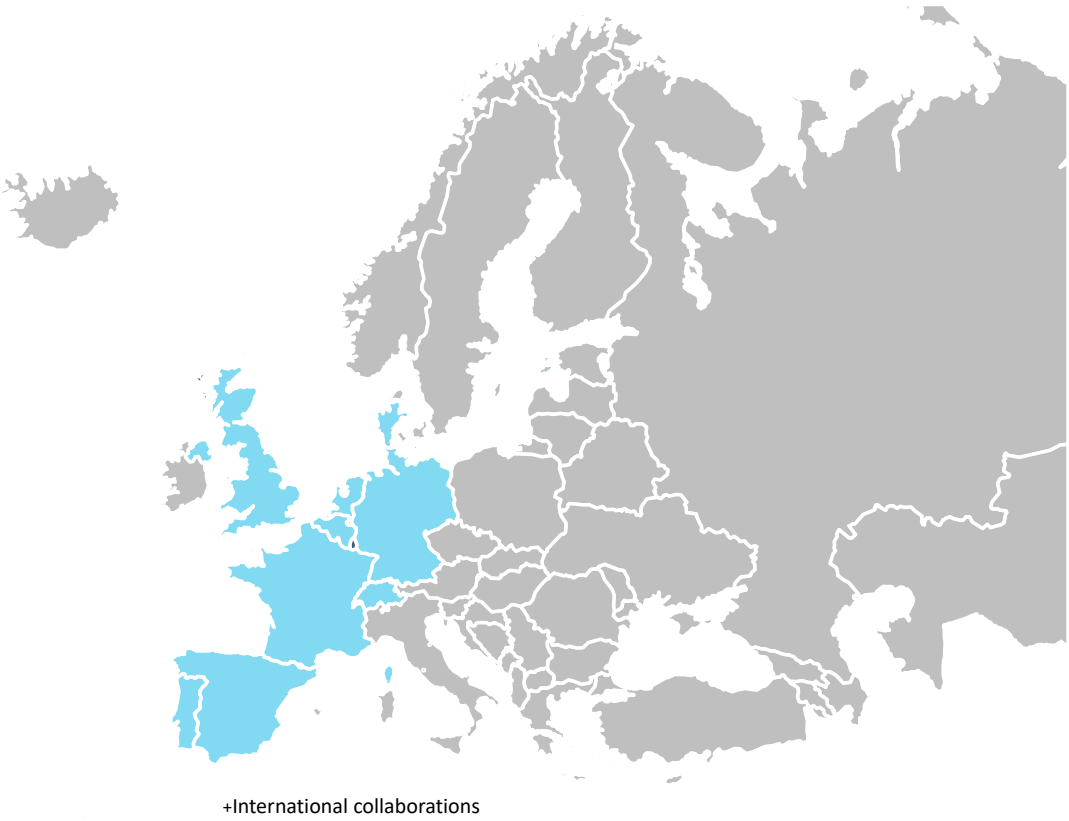

Figure 5. Countries or regions where AF have been developed

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4.3.4 CONFORMITY BASIS

Most of the analysed frameworks operate on a voluntary basis. The use of the framework provides some secondary benefits to the developers, such as the addition to a curated library, increased exposure, or receiving a quality seal. Four frameworks have been identified to work on a mandatory basis. *mHealthBelgium* and *BfArM* frameworks are mandatory if apps want to strive for financing/reimbursement by the national authorities but voluntary otherwise. The same applies to Switzerland, where the profile for the technical connection between an app and the Swiss Electronic Patient Record (EPR) will become mandatory in the midterm. In the Catalan health system, health apps are required to follow the *Tic Salut Social* certification process if they aim to be integrated in the publicly-funded health system. This integration refers to exchanging data from the health app to the EHR, specifically the PHC EHR called ECAP. Integrating the health app into ECAP provides different benefits: 1) health care professionals can prescribe the health app; 2) health care professionals can access some of the data captured from the health app through ECAP; 3) patients-health care professional relationship is reinforced.

Since December 2019, insured persons in Germany are entitled to Digital Health Applications (DiGA) care, which can be prescribed by doctors and psychotherapists and are reimbursed by the health insurance companies. The prerequisite for this is that the DiGA has successfully undergone the mandatory assessment developed by BfArM and are listed in a new register of reimbursable digital health applications (DiGA directory).

4.3.5 TARGET AUDIENCES AND VALUE PROPOSITIONS

Several frameworks are addressed to health app developers, health professionals, and citizens/patients, while some only aim to serve as a guidance for app developers. The frameworks mainly aim to increase confidence in citizens and health professionals regarding the use and adoption of health apps. For developers, several AFs[57] offer the possibility for the app to be included in a library app together with a quality seal. Furthermore, some of them[58] offer a detailed results report which can be used to improve certain aspects of the app. The inclusion

[57] The Andalusian Safety and Quality Strategy in Mobile Health Apps, Tic Salut Social, mHealthBelgium, MySNS Selecção, GGD Appstore, ORCHA Review process, , AppCheck

[58] Detailed results report: Andalusian Safety and Quality Strategy in Mobile Health Apps, Tic Salut Social, AppCheck

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of the app in app libraries brings forth several benefits such as reaching a wider community, increasing the appeal to commissioners, or a higher click-through rate to the app markets.

4.3.6 ASSESSMENT SUBJECT

Most of frameworks are used to assess health apps in general, lifestyle and wellness apps. Few frameworks have been developed for specific use cases. The *MindApps.dk* is dedicated to mental health apps, while *DiaDigital* (App Check) is used to assess diabetes apps and *PneumoDigital* (App Check) for respiratory diseases apps. Some of them have criteria that can be applied only to apps that are certified as medical devices and have CE certification (e.g., *mHealthBelgium*). The Bertelsmann Stiftung developed the *AppQ* set of quality criteria DiGA that are subject to the scope of the German Medical Devices Act (MPG) or has a comparable approval by a foreign authority for medical devices, e.g., by the Food and Drug Administration.

A special case is constituted by the *APPKri* framework that was created by the Fraunhofer Institute for Open Communication Systems. The framework is a comprehensive meta-catalogue of criteria for evaluating health apps designed for patient organisations or other groups that wish to engage in a systematic evaluation of health apps. The organisation developed a platform where users can compile specific assessment criteria catalogues suitable for their target groups and objectives and can choose from several hundred criteria available.

4.3.7 ASSESSORS

Some frameworks are intended for self-assessment, serving as a guideline for developers, while others rely on owner assessment or third party-assessment by established experts. A number of frameworks require both self-assessment and owner assessment. The *Publicly Available Specification (PAS) 277: 2015* by the British Standards Institution contains guidelines for app developers, mainly intended as self-assessment and it covers the stages of the app life-cycle project, including development, testing, release, and update. The owner assessment is performed in some cases by experts from within the organisation that developed the framework, while in other frameworks organisations collaborate with external assessors. For example, *Tic Salut Social* has extended collaboration with experts from various fields, where physicians, nurses, psychologist, experts in physical education and sports, technical developers, usability experts and data protection experts are taking part in the assessment process. For the *MindApps.dk* framework that has a specific focus on mental health apps, the process includes a review where at least two independent therapists and a data security expert from Centre for Telepsychiatry review the app. However, this also prolongs the assessment as for each assessment new relevant therapists must be found.

Self- and/or third-party assessment
• PAS 277:2015 Health and wellness apps (BSI) • Evidence Standards Framework (NICE) • Good practice guidelines on health apps and smart devices (HAS)

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• Criteria catalogue for self-declaration of the quality of health apps (eHealth Suisse) • AppKRI (FOKUS) • AppQ (Bertelsmann Stiftung) • Continua Design Guidelines (CDG) • cMHAFF (HL7) • Report of the Working Group on mHealth Assessment Guidelines (EC) • ISO/TS 82304-2 Health and wellness apps (CEN/TC 251 and ISO/TC 215)
Self- and owner assessment
• Andalusian Safety and Quality Strategy in Mobile Health Apps (ACSA) • DAQ (NHS Digital) • MySNS Selecçao (SPMS) • AppCheck (DiaDigital and PneumoDigital) (ZTG GmbH) • My Health Apps (PatientView) • Our Mobile Health • Mindapps.dk (Centre for Telepsychiatry)
Owner assessment
• ORCHA Review process • Accreditation Service and TICSS guarantee certification (Tic Salut Social) • GGD AppStore (GGD-GHOR) • BfArM • mHealthBelgium • ISYS score (iSYS Foundation) • Medappcare Quality Approach

Table 5. Frameworks classification by assessment type

4.3.8 DURATION OF ASSESSMENT

The duration of assessment varies considerably between frameworks. In some cases, the validation can take less than a week (e.g., *mHealthBelgium*), while in others it can take up to three months (e.g., *MySNS Selecção*). Several factors come into play to determine the duration of assessment. A third-party assessment by external experts can prolong the process, whereas an automated API platform usually speeds up the evaluation. While all its reviews are undertaken by a professional review team, ORCHA uses AI tools and techniques to support the validation of the reviewer findings. The average time to complete an ORCHA Baseline Review is two hours and, overall, a full ORCHA Enhanced Review would typically be capable of being completed within the 2-3 day-long period.

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During the COVID-19 outbreak, multiple apps have been developed in a very short period of time, and given the situation, it may not be possible for governments or other agencies to conduct an in-depth assessment. This constitutes clearly a challenge for health apps quality in the context of public health emergencies.

4.3.9 ASSESSMENT PROCESS

Several frameworks have a clearly defined assessment process. Most of them yield either a quantitative outcome represented by a general score, or a qualitative outcome, represented by a quality seal or a recognisable vignette.

The Andalusian Safety and Quality Strategy in Mobile Health Apps includes both self-assessment and an assessment carried out by the committee of Agency's experts, and the outcome of the assessment framework is qualitative (Pass / Fail schema), represented by the award of the *AppSaludable* Quality Seal, which guarantees the reliability of the mHealth app. The process follows a qualitative model according to the degree of compliance with the 31 recommendations, where in each recommendation there are requirements that are mandatory and must be met to obtain the Distinctive and other criteria that are not mandatory but are recommended to be met and that provide a plus of quality to the apps that go through the process. To obtain the Distinctive, the app must comply with 100% of the mandatory requirements and at least 60% of the non-mandatory ones. At the end of the process, full assessment reports are generated and shared with the app development team.

For *Tic Salut Social*, the accreditation process has three phases that include the review of the application, an initial technical validation together with a functional validation, and a last technical accreditation. The corresponding accreditation certificate is delivered together with the detailed results report of the accreditation made.

In the *AppCheck* assessment, besides the general process that includes several steps similar to the ones above (self-assessment, expert assessment), the organization offers the possibility of a teleconference in which all testers can participate.

For *MindApps.dk*, each question in the assessment can be rated with a score from one to three. The assessment is performed in the *AppChecker* platform that will ultimately calculate the average score. The final score can range from zero to three stars. The score is an average of the points the therapists have given based on The *App Checker*'s twelve questions. The score cannot stand alone and must be seen in context with the rest of the assessment. For example, an app can have excellent background information, clinical quality, and design, but if there are some features missing, it will not get three stars.

For *BfArM*, the procedure is designed as a fast track. The core of the procedure is the examination of the manufacturer's information on the required product characteristics - from data protection to user-friendliness - as well as the examination of evidence to be provided by the manufacturer for the positive care effects that can be achieved with *DiGA*.

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DAQ-NHS Digital contains questions designed by experts from technical and policy backgrounds, and cover national standards, regulations, and industry best practice. The number of questions depends on a product`s complexity, potential clinical effectiveness, and data protection responsibilities. The process includes four steps. The first step considers the eligibility of the app, where NHS has defined specific requirements. The second step includes register details about the developer organization and the submitted product. In the third step, a technical assessment takes place, where several questions are asked. In the fourth step, if the app has successfully completed the technical assessment, the product is published in the NHS Apps Library.

For *mHealthBelgium,* the app assessment framework is a validation pyramid with 3 levels. An app always enters at the lower level, M1, and can climb in hierarchy via M2 to the top level, M3. To be allowed to the next level, the app first need to fulfil all criteria of that level. Every level has its own automated process with predefined flows.

MySNS Selecção assessment process contains three steps. The first and second step are dedicated to the health app owners, to review all the framework requirements needed and fill out the form application to submit the app. In the third step, the applications are evaluated by a group of experts in terms of performance, security and public utility using qualitative scores. If the apps comply with all the evaluation criteria, they obtain the quality seal "Selected" and will be part of the *MySNS Selecção* library available in the website. The apps that need to perform improvements in some criteria, they will acquire the "Pre-Selected" seal.

The ORCHA Review Process consists of seven stages described in high detail on the ORCHA website. The aim of ORCHA scoring is ultimately to reward best practice and highlight poor practice or no compliance. The mechanisms used are designed to ensure that, wherever possible, the score reflects relative performance and properly differentiates between similar apps. After a weekly analysis of Apps available on the App Store/Google Play in the "Health, wellbeing / fitness and medical section", the selected apps are sorted within 350 categories. Apps are classified according to their area of focus and the functional capabilities and the apps are checked for functionality features and review domains. The scoring elements are used to derive a series of 'section scores' which combine to create an overall ORCHA Score. Some scoring questions earn positive ('value') points and some earn negative ('risk') points. Each scoring question has either a Risk implication or a Value implication. The quantum of the Risk or Value implication is decided by the relevant tariff: Risk area tariffs range from small, medium, high or exceptionally high. Value area tariffs range from small, medium or high. In addition to the base Tariff, some Risk and Value related questions attract a ratchet that will increase the relevant Tariff based on certain related app characteristics. The analysis results in a quantitative score based on the answers to each of the questions in the three review domains. During the cooling off period following their Review, the Developer is able to raise any issues or concerns with the Review Team, and, if they are able to rectify any of the elements that have negatively impacted their initial Review, they can in this period do that and the relevant element will be re-assessed before the Review goes live. Finally, ORCHA has a feedback mechanism on all supported platforms for end users (professional and none professional) to alert to any inaccuracies or errors that end-users believe may be present in the Review or more broadly any wider concerns

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or risks they have identified in using the app. ORCHA usually replies to all queries within a 7 day-long period.

My Health Apps review consists of two stages. In the first stage, the assessment is performed either by the developer (self-assessment) or by the users or healthcare communities who want to include an app in the My Health Apps repository. To submit an app, an online survey available in multiple languages must be filled in. In the second stage, background checks are being carried out by *PatientView*. The approved apps are published on the website under three main categories.

For ISYS Score, apps are included through 4 procedures. The first, and most relevant, is by searching for the 10 best results offered by Google, by ICD-10 category (14 categories), which represents a total of 140 Apple Store apps and 140 Google play apps (total 280 Apps captured every December). Those that exceed the inclusion criteria are selected below. The second is on the recommendation of patient associations. Every year, a group of 30-40 patient associations are consulted to make their recommendation. The third is to re-evaluate the top 5 from the previous year. The apps are published in the yearly iSYS catalogue.

4.3.10 SUSTAINABILITY/BUSINESS MODEL

Some companies perceive fees for the assessment and inclusion in the website repository. The fees often vary considerable between initiatives. Several frameworks do not perceive any fee. For example, the development of the *AppQ* framework was funded by the German Federal Ministry of Health and it is maintained by the Bertelsmann Stiftung, a private operating foundation. *MySNS Selecção*, the Portuguese framework, is currently financed by the Health System Central Administration but it will probably transition into a self-sustainable model considering evaluation fees for services. Some of the frameworks are intended only for self-assessment purposes and are available online. *The Mindapps.dk* is also a publicly funded framework to support and extend the use of apps across psychiatric care.

Companies who want to get the *mHealthBelgium* quality label and hence be visible on the portal, pay a yearly fee of 1000 euros (25% reduction for those who are member of *Agoria* and/or *beMedTech*). This budget will be used to maintain the platform and is an incentive (at least yearly) for the providers to keep the app info up to date.

AFs where fees are charged for accreditation services
- Accreditation Service and TICSS guarantee certification (Tic Salut Social) - AppCheck (DiaDigital and PneumoDigital) (ZTG GmbH) - Continua Design Guidelines (CDG) - ORCHA Review process - IsysScore ISYS score (iSYS Foundation)

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- Medappcare Quality Approach - Our Mobile Health
AFs with free assessment / self-assessment
- Andalusian Safety and Quality Strategy in Mobile Health Apps (ACSA) - DAQ (NHS Digital) - MySNS Selecção (SPMS) - Evidence Standards Framework for Digital Health Technologies (NICE) (guideline) - Mindapps.dk (Centre for Telepsychiatry) - PAS 277:2015 Health and wellness apps (BSI) (guideline) - AppQ (Bertelsmann Stiftung) - My Health Apps (PatientView) - ISO/TS 82304-2 Health and wellness apps (CEN/TC 251 and ISO/TC 215) (guideline) (For certain use cases a fee may apply) - BfArM DiGA-Fast-Track and Guidance Document - Report of the Working Group on mHealth Assessment Guidelines (EC) - Good practice guidelines on health apps and smart devices (HAS) (guideline) - GDG AppStore (GGD-GHOR) - AppKRI (FOKUS)

Table 6. Frameworks classification by payment type

The ISYS Score Business model (iSYS Foundation)

The foundation perceives fees for the assessment and inclusion of the app in the health catalogue.

- Individuals: € 75
- SMEs with less than 5 years of experience: € 250
- Already established companies / Large companies: € 500

Certain non-profit entities, such as civil associations, will receive a 50% discount

The Accreditation Service and TICSS guarantee certification Business Model (Tic Salut Social)

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Accreditation rates are perceived for the assessment. The accreditation process, blocks, rates, and payment model are described in a guide published on the TIC Salut Social website.

- Phase 0 Review of the application - free
- Phase 1 Initial technical validation and Functional accreditation- 999,00 €
- Phase 2 -Technical accreditation - 2.000 €

Other considerations and additional charges:

If reviewed separately,

- Basic Security Module: 975 €
- Basic Technological Module: 975 €
- Basic Usability Module: 975 €

Surcharge applicable to applications that exceed the standard volumetry. The additional screen surcharge will be applied: 60 €

Surcharge for each external device with which the app interacts. The device is not certified: 170 €

Revalidated. If the application does not pass any of the accreditation blocks, the process again can be reviewed again, paying 50% of the cost: 50%

Accreditation review (The duration of the accreditation will be annual. The mHealth Office will decide if the accreditation should be carried out again or if it is not necessary. The developers are committed to notify the mHealthOffice of the new versions and changes that involved): 100%

Security audit (Depending on the criticality of the application, the mHealth Office may request a security audit): evaluated in each case.

The ORCHA Review Process Business Model

ORCHA helps governments develop and deliver national health app accreditation programmes, from market insight reports to full implementation roll-out plans.

ORCHA generates revenue through app libraries and professional platforms for clinicians. ORCHA also receives moderate fees for the independent reviews. Whilst ORCHA does charge

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for detailed results of the assessments, it undertakes the majority of reviews for free and Developers/Product Owners can access the core and publicly available results of these for free via their [My ORCHA] account. ORCHA also provide the results of reviews free to Charities and most ORCHA 'Client Portals' are freely accessible to the relevant supported populations.

The ORCHA Fast Track Review allows developers to have their app included in the review schedule and apps with low download numbers to have increased exposure. It assesses over 300 review elements in the three core review domains: Data and Privacy, Professional assurance, and Usability and Accessibility. ORCHA offers a detailed improvement report and a consultation with the review team to discuss the review conclusions. [£499 + VAT]

The Prelaunch Review enables developers to have their app reviewed if the app has not been yet published or a new version is about to be released. The review offers a detailed improvement report and a consultation with the review team to discuss the review conclusions. [£678 +VAT]

ORCHA Consult, following Review or Pre-Launch Review: ORCHA Consultation Package £149 +VAT charged hourly: it provides innovators with an opportunity to discuss the findings of the review with a member of the team at ORCHA. Developers can then choose to make changes and request a re-review (within 8 weeks of the original review) before their app review is included on the ORCHA Microsites. ORCHA Consultation Package fees starting at £600 +VAT per day - ORCHA can provide access to a range of subject matter experts to support your bespoke requirements. Examples of support include access to experts in Health Economics, Clinical Evidence, Creating value propositions, Business modelling, Data Security Regulations, Data privacy Regulations, Medical Device Regulations, and Clinical Safety.

This framework offers products for health and care professionals, including an *App Library Pro Account*, which helps professionals to recommend quality assured digital health solutions directly to their patients and service users. Professionals can search its App Library, with the reviewed health and care apps, to either learn about apps for different health conditions, or to find the most relevant apps to recommend to their patients.

ORCHA developed the free resource for schools '*Digital Healthy Schools Programme*', which aims to train young people in mobile health. This initiative is commissioned by local councils, to empower young people to embrace and responsibly use apps to support their own health and wellbeing.

4.4 Insights from the webinar with assessment framework owners

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Representatives from eight AFs owners[59] kindly joined the first webinar hosted in June 2020. The webinar offered several useful insights, regarding different topics of interest.

Integration of health apps into the health systems

- Apps are now more in the mainstream; the health systems are moving towards it. Bringing in the conformity assessment, the common criteria, then how do you start certificating the app so it can be prescribed through a national framework? Both sides (health system: prescribe it as a drug, device, etc.; patient: safe use of the app). The information currently mandatory in the apps is not enough for enabling prescription systems through national frameworks.

Dialogue and cross recognition between assessment frameworks

- The scenario in apps assessment is very fragmented, we have disconnected initiatives.
- When thinking about a potential common set or framework, it is needed to go beyond theoretical approach and be aware of real scenarios and needs.
- Lack of information about the pool of entities that are doing assessment processes, how the process is performed, which criteria are checked.
- In apps quality there is so much work to do, a single organisation cannot manage it.
- We should consider the apps developers. For them it is not feasible to address so much assessment schemes. Two possibilities: try to get to a common assessment framework (it might not be quite realistic); other possibility might be to rely on other institutions through cross recognition elements (e.g., through twinning projects), for those elements not depending on the country regulation.
- Confidence in health apps is crucial to adoption and promotion within the health system. Having some recognized framework is important. For example, the ISO initiative is working on a common set of generic criteria, that is globally applicable, to simplify that process.
- There is a real value in getting commonalities across AF on the criteria (beyond the details on how the assessment is done).

[59] Andalusian Safety and Quality Strategy in Mobile Health Apps, Accreditation Service and TICSS guarantee certification -Tic Salut Social-, MySNS Selecçao, App Check (DiaDigital and PneumoDigital), ORCHA Review process, CEN-ISO/DTS 82304-2 "Health and wellness apps - Quality and reliability criteria across the life cycle, cMHAFF: Consumer Mobile Health Application Functional Framework, Continua Design Guidelines (CDG).

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- If we had a common framework, maybe our specific frameworks might have more value, the fact of passing the accreditation process might be given more value.
- From standards organization perspective, willingness to ensure that standards learn from apps and developers; to drive consistency and Digital Single Market as real opportunity for delivering more value.
- There is a challenge because there are certain elements of the assessment that are global (questions that you can ask all the products) and certain that are national/regional, with specific regulations; layers approach.
- Apps quality: to enable apps to become economic viable. Example: small sub-set of questions depending on where you are... It makes it quite efficient, powerful.
- Each organisation has a different mission and vision. The final thing which is common for all AFs and turns an issue is how do you monitor and manage the changing landscape of digital health, from an individual digital health solution perspective. How do you ensure quality on an ongoing basis? How do you ensure quality out of regulations and standards? Continuous review as a key aspect.
- Helping people to search and find the best product for their personal needs, rather than just focusing on the assessment criteria. Listing app functions; who is supporting the product, where do the product has more impact, for which population, etc. On the other hand, several AFs are looking at the whole business process of apps assessment (not only the criteria): training, interaction between developers and users under criteria.

Ethical and cultural issues in the assessment frameworks

- Does any framework address cultural issues? It seems not, at least not in an explicit or labelled way.
- How the AFs assess compliance with wider ethical issues (gender, accessibility, equity and digital divide...)? Impact of health apps on the doctor-patient relationship? It is easier to provide guidance on more technical guidance (data protection, privacy, security...), but some of the wider aspects are not covered.
- Ethical issues might bring in more around organizational standards (suppliers, other organisations around the health system). rather than individual products (apps).
- The acknowledgement of non-technical issues by different stakeholders, e.g., developers is a challenge, it has not been very encouraging in recent experiences.

CE-marking and assessment frameworks

- There are many products that will fall under CE-marking; important role por providing quality assessment.
- The solutions will have to be consistent with both: CE-marking (relevant and helpful) and the rest of criteria in the AF; global markets.
- Some frameworks are playing a role in providing advice and developing tools for medical associations, patient organisations or developers about CE-marked, where they don't have much experience. Many developers are not aware, they are not carrying a CE-marking yet, still a lot of work to be done.

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- Several initiatives from frameworks to adapt to this CE-marking context. As an example, Andalusia (Spain), formal customizable certification process on progress, attention to third party apps, decision tree, process enabling the health professionals prescribing apps in the future (Salud Andalucía app; ClicSalud+); Catalonia (Spain), reviewing accreditation process (e.g., functionality), will launch the mConnecta project; ISO/TS 82304-2 was at that moment in testing phase and developers filling in the questionnaire.
- Importance of third-party assessment: their engagement in the assessment process delivers more value, getting more accurate and trusted set reporting on quality; also giving the app developers value, understanding why and where they can improve. The role of app assessment organisations is going to become more strongly in the upcoming years.
- There are lessons to learn from regulatory environments (e.g., United States of America); connection with health economics, and societal and ethical impacts.

4.5 Health apps assessment and reimbursement: the example of Germany

Germany is at the forefront in terms of concrete legislation in place (Digital Supply Act – *Digitales-Versorgungs-Gesetz*, DVG, which came into force on 19 December 2019[60]) on reimbursement of digital health applications (DiGAs). DIGAs are defined medical devices of risk class I or IIa which support the detection, monitoring, treatment or alleviation of diseases or the detection, treatment, alleviation or compensation of injuries or disabilities.

The law introduced for the first time the "app on prescription" concept, reimbursable by statutory health insurances. The law has a high impact on the German statutory health insurance system as one of the largest in the world, with approximately 90% of the population (i.e., roughly 75 million people) in Germany being covered by statutory, state-funded health insurance.

To become reimbursable, the app needs to pass an approval procedure at the *BfArM*. Following its guidance ("*Leitfaden*"), the *BfArM* assesses whether the app provider has provided proof that their digital health application fulfils the following requirements: safety, functionality, quality of the medical device, data protection, state-of-the-art data security, and positive effects on care. The *BfArM* will make a decision regarding the provider's request within three months of receiving complete application documents.

[60] https://www.bundestag.de/dokumente/textarchiv/2019/kw45-de-digitale-versorgung-gesetz-664900

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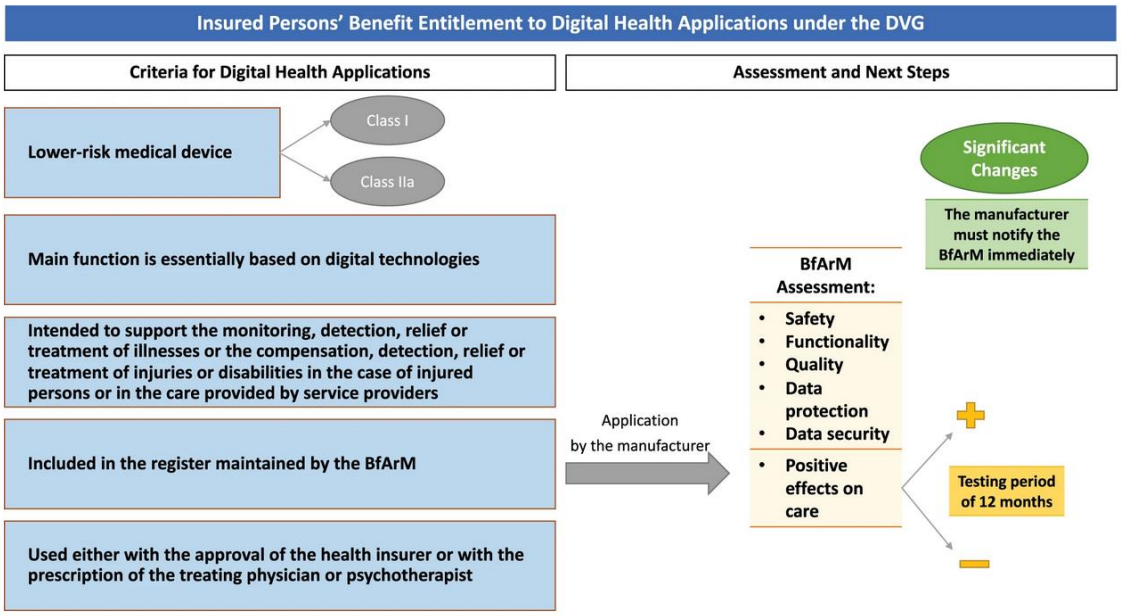

Figure 6. Criteria for digital health applications (left column) and assessment by the *BfArM* to be included in the register and next steps (right column).

Source: Gerke, S., Stern, A.D. & Minssen, T. Germany's digital health reforms in the COVID-19 era: lessons and opportunities for other countries. npj Digit. Med. 3, 94 (2020). https://doi.org/10.1038/s41746-020-0306-7

If the app meets all requirements except for the last one, i.e., positive effects of care, it can be included in a register maintained by *BfArM* for a preliminary (testing) period of 12 months, during which statutory health insurances will reimburse the costs provisionally. In order to qualify for cost reimbursement, providers of health apps have to generate proof for positive effects on care for their respective apps within these first twelve months. Such positive effects could be related directly to medical outcomes for patients or to process and structural improvements. Providers of health apps which already generated proof for these positive effects can now apply at the *BfArM* to become component of German reimbursed standard care directly.

The German experience is a positive one, albeit with certain limitations resulting from the definition and scope of the law, which for now excludes non-medical devices as well as digital health applications that are categorised as class IIb or class III devices, e.g., certain clinical decision support software.

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4.6 Role and experiences of patient organisations regarding the quality of apps

PROFILES OF PATIENT ORGANISATIONS

The European Medicines Agency (EMA) defines patient organisations as "*Not-for profit organisations which are patient focused, and whereby patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies*"[61].

Patient organisations exist on different levels: local, regional, national, European and international. There are patient organisations that are somatic oriented, representing patients with chronic diseases such as diabetes or cancer, and others focused on mental health. The main activities of patient organisations can be summarised in four different areas: *policy, capacity building and education, peer support, and research and development*[62]. They represent the collective interests and outreach of the members and patient communities working as national, regional or local bodies to help policymakers understand the experience of living with a disease or a condition, and they serve as legitimate stakeholders in health-related policies. Patient organisations are experts in channelling the voice of patients through representation, mobilisation and empowerment, trying to advocate political commitment and public support for specific patient and health of general population.

European Patients Forum (EPF)[63] can be seen as an example of an umbrella organisation with 72 pan-European disease-specific patient organisations and national coalitions of patient groups from several EU Member States. The EPF's role is to be the united voice of patients and the key interlocutor with the EU institutions on cross-cutting issues affecting all patients.

There are also online patient communities whose communication channels are on the Internet, such as in social media or discussion forums that support networks for patients and disseminate information. An example is PatientsLikeMe[64], a personalized health network with more than 750,000 members who create 43 million data points.

[61] European Medicines Agency, Stakeholders and Communications Division, (2014). Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/12/WC500018099.pdf

[62] Sienkiewicz D, van Lingen C. The added value of patient organisations. Report European Patient Forum, 2017.

[63] https://www.eu-patient.eu/About-EPF/what-is-a-patient-organisation/historical-context/

[64] https://www.patientslikeme.com/

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PATIENT ORGANISATIONS CASE STUDIES

Experiences about health apps were collected from five patient organisations in Europe through digital interviews and email communication: PatientView, European Patients Forum, Danish Lung Association, Norwegian Diabetes Association, and Danish Multiple Sclerosis Society. Furthermore, a sixth case study was developed based on a position paper from the International Diabetes Federation (IDF) Europe.

PatientView[65] is a patient-centred European-wide framework organisation sustained by public funding and donations. Their aim is to promote the benefit of patients and better care, and maintains a collaborative, non-profit organisation. Since 2013, PatientView has been taking practical steps to help individual patients find trusted health apps, based on recommendations by recognised patient organisations. They provide directories, a toolkit helping individuals to choose an app, events and research that identifies unmet needs in different therapy areas where patient group recommend and create apps (visit http://myhealthapps.net/ for more details, it has been one of the reviewed AF). The organisation aims to give patient organisations a platform to share their voice on apps.

Regarding the future, the organisation has stated that health systems will only recommend or prescribe apps when clinicians, payers and policymakers feel there is a robust clinical assessment in place to give confidence for doctors to recommend or prescribe apps. In addition, patients will only "comply" with recommended or prescribed apps, if they genuinely are useful in addressing an unmet need identified and prioritised by patients. They see challenges with health apps regarding the lack of transparency, the organisation or company that funded and created it and advised the medical content.

European Patients Forum (EPF) is an umbrella organisation representing 72 patient organisations and around 150 million patients across Europe. The goals of the organisation include the digitalisation and establishment of a policy framework, empowerment of patients through digital innovation and self-management, safe digital health on all levels and co-design and accessibility. EPF wants to increase their work on health apps, however there is a general concern about patient safety and data protection. EPF tries to facilitate engagement and advocate for quality assured frameworks and reliability. The reliability of health apps is one of the key points for the future, together with how data are collected, stored and used. EPF is involved in discussions on data space, data protection, standardisation and interoperability at European level.

[65] https://www.patientview.org/#/

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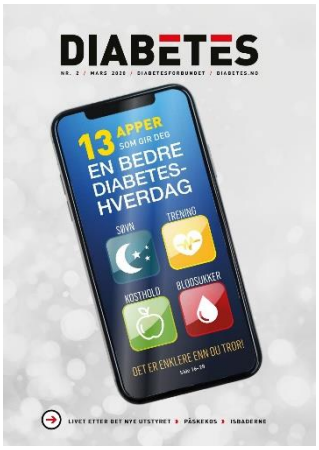
The **Danish Lung Association (DLA)** is a national organisation with 22,000 members. DLA works for implementing digital treatment and services for lung patients in close contact with policymakers. Their approach consists on outreaching of large groups of patients through digital tools that must be relevant and useful for their daily life. DLA advocates for user-driven innovation focusing on the needs of the citizens and has been represented with users/patients in several development projects. The COVID-19 situation revealed needs for digital tools for maintaining the services to lung patients, offering services such as digital training, digital meeting rooms for patients, digital choir and nutrition advices. Another emerging area is digital smoking cessation programs, where patients can participate from home. However, it is important to address the questions: "What apps are needed?" "What is already available?". DLA also considers already existing digital platforms and apps might be useful. The organisation addressed the challenge of how to make health apps become a part of the health systems and stressed that change management is needed. Digitalisation in general requires an effective collaboration between all involved stakeholders: patients, clinicians, municipalities, health regions and policymakers. Clinicians must be open to recognise and use the digital tools available.



The **Norwegian Diabetes Association (NDA)** is a national organisation with 30,000 members that was established in 1948 and is a member of the International Diabetes Federation. NDA has a Technical Expert group, as diabetes therapy is associated with several medical devices and technology. A user survey among the members showed that reliable consumer-friendly tools were wanted with a reference to validation. NDA has been a partner of research studies with patients and health professionals, comparing what patients and clinicians discuss on social media. There are researchers associated to the organisation that establish guidelines and criteria for assessment and evaluation of mHealth apps through a systematic approach[66]. In a recent volume of the members' magazine Diabetes[67], 20 pages (in Norwegian) were dedicated to diabetes-related health apps, presenting an evaluation of 13 specific apps for self-management, lifestyle and activity.

Figure 7. The NDA magazine

[66] Larbi D, Randine P, Årsand E, Antypas K, Bradway M, Gabarron E. *Methods and Evaluation Criteria for Apps and Digital Interventions for Diabetes Self-management: Systematic review.* Journal of Medical Internet Research (forthcoming). doi:10.2196/18480.

[67] Diabetes vol.2 (March 2020). The Norwegian Diabetes Association. https://www.diabetes.no/nyheter/nyheter-2020/mobilapper/

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The **Danish Multiple Sclerosis Society (DMSS)** is a national organisation with 65,000 members, which represents over 1% of the Danish population. They were a partner in a study[68] in 2017apps for Multiple Sclerosis (MS) patients that showed that fatigue and sleep were factors that wearables helped participants to better understand and act on. The wearable gave a better understanding when MS patients were feeling exhausted, which made it easier for them to plan their everyday life[69]. The study also showed that the patients found relevant to use wearable-data in a clinical context and communication with health care professionals[70]. Apps, wearables, activity trackers and digital solutions such as smartphones can be an aid for a better lifestyle. Many MS patients in Denmark have a high level of eHealth/digital literacy[71], which allows them to use portable and wearable technology in a satisfactory way and collect personal information. DMSS made a survey on privacy and storage of data and the results showed that better data storage was wanted. For many apps, data storage and privacy were often unclear and not easy to understand. Regarding trends, there are several digital solutions for MS patients, but few of them are tailored and are accurate enough for a MS patient's everyday life. Apps in native language (terminologies, vocabulary) underlines the importance of the accessibility and user-friendliness for the patients, confirmed in another study with another patient organisation[72]. DMSS does publish recommendations for health apps on their webpage, in a generic format and not usually recommend specific apps, unless they are of high quality or connected to research and validated.

The **International Diabetes Federation (IDF) Europe**, who is a member of #Digital4Care by Health First Europe[73], published a position paper[74] in 2017 on mobile applications for diabetes, The IDF Europe stated that these new technologies deserve the same attention as other advancements in medical therapy. The paper stated there is an unexplored potential in the ability of how apps can make an impact on people living with diabetes. Diabetes self-

[68] MS Life Logging, (2019). The Danish Multiple Sclerosis Society.

[69] Bergien SO, Fuglsang CH, Kayser L, Lynning M, Skovgaard L. (2019). "MS Life Logging: How wearables can empower and benefit people with multiple sclerosis in their everyday life".

[70] Bergien SO, Fuglsang CH, Kayser L, Lynning M, Skovgaard L. (2019). "MS Life Logging: People with multiple sclerosis' and healthcare professionals' view on wearable data in a clinical context".

[71] Osborne R, Kayser L. (2018). Skills and characteristics of the e-health literate patient. BMJ: British Medical Journal 361

[72] Smaradottir B, Fagerlund AJ, Bellika JG. (2020). "User-centred Design of a Mobile Application for Chronic Pain Management" Stud Health Techn Inform.

[73] http://healthfirsteurope.eu/wp-content/uploads/2019/06/Members-reflection-on-digital-health-2.pdf

[74] http://idf.org/component/attachments/?task=download&id=1063

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management involves psychological and behavioural factors connected to challenges in daily life. Apps may aid individuals through difficult periods by providing structure and social support for achieving glycaemic control.

The position paper targeted the quality and usefulness of the apps. A study referenced in the paper evaluated 65 apps for self-management of diabetes and found that only 9 could be useful for a successful self-management of diabetes[75]. It was mentioned that app documentation of diabetes therapy and behaviour might help identifying patterns and reveal actions and habits with consequences on diabetes self-management. This can have an educational effect and create a new level of awareness for the individual. The position paper also targeted interoperability, and adaption of the apps to their targeted audience. Further, accreditation and content quality were addressed, and the importance of knowing who developed the product and appropriate validation and verification procedures. Errors in algorithms calculating insulin doses can be fatal when they lead to severe hypo- or hyperglycaemia. The position paper stated that "A well-suited app could transform a mobile phone into a medical device helping ease the burden of diabetes, preventing complications and improving a patient's quality of life". However, it concluded that most apps had not been tested or evaluated for improvements in health outcomes and should be carefully used and promoted. Validated apps should be recognized by authorities, industry and other stakeholders and as a central element in mHealth. The position paper provided also a few specific recommendations for an individual patient.

Finally, the position paper of IDF Europe highlights user-involvement and co-design for the development and evaluation of apps and encourages developers to include patients and patient organisations.

4.7 Considerations about the mHealth market

This section of the report seeks to highlight some key aspects related to the mHealth market, which might have influence on the adoption and implementation of health apps. Sometimes public authorities are not fully aware of these considerations and their impact on the consolidation of mHealth initiatives promoted by governments.

MHEALTH MARKET AND VENDORS: CONNECTIVITY, PLATFORMS, APPS

[75] Brzan PP, Rotman E, Pajnikihar, Klanjsek P. (2016). "Mobile applications for control and self management of diabetes: A systematic review" J Med Syst, *40*(9):210.

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mHealth market in terms of vendors can be roughly divided into 3 categories: providers of connectivity, providers of digital health platforms and providers of applications.

Connectivity solutions include products and services that are used for collecting data from medical devices, transmitting this data to health professionals and caregivers and enabling the data to be used by digital health platforms. Important players include *Apple, Microsoft, Validic*, to name a few.

Digital health platforms are software solutions that enable the remote delivery of healthcare services. There are various types of care delivery platforms available on the market. General-purpose platforms can be adapted to a wide variety of use cases and are often used as the basis for developing therapy-specific mHealth products.

mHealth application providers are application developers for, most often, single use-case – i.e., diabetes prevention, hypertension monitoring, COPD monitoring, ECG diagnostics, digital therapeutics, etc. This category is most versatile since there is an endless number of problems that are addressed by different use-cases in healthcare. There are more than 300,000 applications available in app stores according to Reseach2Guidance report from 2017[76], and often applications get developed for wellness (85%) while in medical area (15%), most often are apps in disease management, women's health and medication management.

APP DEVELOPER PROFILES

There are a lot of different companies trying to enter digital healthcare market by developing a solution based on mobile communication. In general, they can be divided into two groups: the ones with already established footprint in healthcare market and the ones that are new to healthcare market. From the latter group it can usually be identified start-ups trying to solve a problem they identified with an expert in healthcare field or already established mobile app developers trying to enter healthcare market.

From companies already present in health IT market it can be seen companies developing mobile versions or extensions of their proprietary software (like *Hospital Information Systems HIS*, etc...) and there are incumbent health IT system integrators developing purpose built mobile applications for national health systems. The knowledge of health IT system landscape in country is important for applications integrating with health system.

[76] https://research2guidance.com/325000-mobile-health-apps-available-in-2017/

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Another categorization that can be correlated, but not necessarily, to above presented segmentation is the knowledge of business processes in healthcare (no inhouse expertise or in-house expertise).

MHEALTH APPLICATION LIFECYCLE

Factors affecting mobile application lifecycle are: regulatory grade of application (non-medical or medical application), type of mobile application (prevention, diagnostic, therapeutic, monitoring), number of supported operating systems, number of phones tested with, peripherals application is connected to, and number of releases per year.

To ensure mHealth application lifecycle with constant updates, distribution and continuous operation, all factors need to be managed in parallel and tested accordingly to ensure safety and trustworthiness. This all together is contributing to more complex lifecycle than web applications and it is requiring more resources throughout the whole lifecycle, beyond application development.

COSTS ASSOCIATED WITH MHEALTH SOLUTIONS

Costs associated with mobile application can be divided into two major categories: development and implementation costs and lifecycle costs. Development and implementation are initial costs associated with application creation, while lifecycle costs are the costs associated with application maintenance from first application release to application phase-out from the market.

Development and implementation costs include: requirements collection and management, prototyping, user experience design, application software design, infrastructure costs for development, test and production environments, application development, application testing, application regulatory certification (if applicable), documentation development, application installation and application integration to existing health IT systems (if applicable). Today the average mHealth application costs $425.000 to develop until launch according to Research2Guidance report on mHealth developers' economics[77].

Costs in mobile application lifecycle include: cost of application maintenance, new features development, analytics monitoring and reporting on usage, application testing against new mobile phone models, application updates and testing related to operating system updates, regulatory updates (if applicable), application security updates.

[77] https://research2guidance.com/product/mhealth-economics-how-mhealth-app-publishers-are-monetizing-their-apps/

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Since lifecycle activities include constant resources involvement in application maintenance, costs associated with lifecycle are usually higher than expected, if compared to web application standards of maintenance costs compared to development costs. It is not unusual that yearly lifecycle costs reach or even exceed initial application development costs (depending on complexity, new features and regulatory grade). It is recommended to assume recurring license costs (or subscription costs) rather than perpetual license costs for mobile applications to ensure safety and quality of applications throughout their lifecycle. This licencing model is recommended to include full coverage of maintenance services, besides corrective maintenance for application features, that are usually not perceived by the end user and include the ones mentioned in paragraph above.

MARKET AND INDUSTRY TRENDS

In recent years, there has been a strong adoption of several consumer-oriented mHealth products. One of the main enablers is Bluetooth LE technology - this has made it possible to launch connected medical devices at similar price points as the non-connected variants.

Tech giants and fitness companies, such as Garmin and Fitbit, are making moves into the health segment since a couple of years back. Apple in 2018 announced that the Apple Watch Series 4 had been cleared by the FDA as a Class II medical device for use as a consumer ECG monitor to detect arrhythmia.

Home monitoring78 is currently evolving into a more advanced care model than it has previously been. Up till now, the main purpose of home monitoring has been to collect more frequent readings in order to monitor the condition, progress and therapy compliance. More data also means more opportunities to create algorithms that can support patients efficiently. Like most industries, the healthcare industry is also beginning to utilize machine learning and AI. For example, several care platform providers are developing algorithms based on behavioural science to create personalised feedback messages to patients. This can include reminders to take medication, recommendations to address certain symptoms and real-time adjustments of the treatment plan to address changes in the patient's condition. It can be used to support the adherence to a therapy or as a therapeutic measure in itself.

Diabetes, hypertension, respiratory diseases and mental illnesses are conditions that will likely benefit from increased self-management and there is a potential benefit from collecting data directly from devices to for example monitor medication adherence, physical activity and social activity. Solutions that collect data automatically will require less effort needed from the patient and will be easier to implement.

[78] http://www.berginsight.com/ReportPDF/ProductSheet/bi-mhealth8-ps.pdf

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4.8 Hub orientations when setting up a health apps assessment framework and evaluation process

INTRODUCTION

Health applications have a high potential to become an important part of the healthcare ecosystem, enabling healthcare services costs reduction, while at the same time improving healthcare quality, and supporting essential aspects such as patient empowerment and remote patient monitoring. For health apps to be integrated in healthcare systems, they need to prove safe, effective, and reliable. In 2015, 73% of countries did not have any system in place to verify the quality, safety, and reliability of health applications[79]. In the past few years there has been an increase in the number of initiatives undertaken to assess health apps. In 2020, the European mHealth Hub took stock of 24 assessment frameworks for health applications across 9 Member States, as well as several European and international initiatives[80]. Moreover, 22 health apps repositories[81] have been identified.

There is a high need of defining assessment frameworks in Member States that do not have any system implemented, as well as increasing effort for mutual or cross-recognition between frameworks to speed up the certification and adoption processes. This section provides distilled key considerations for individual countries, regions, or organisations that want to move forward on their mHealth agenda and would like to develop their own bespoke assessment framework.

An assessment framework in the most generic sense provides a **set of criteria** against which mobile health applications can be evaluated. The **purpose of mHealth evaluations** can be summarised in the following points:

- To ensure broad, rapid, and sustainable patient and citizen access to digital health innovations and assist with consumer decision-making.
- To provide policymakers and funders/insurers with the necessary information to understand the benefits and comparative value of health apps, to inform policy, funding, and reimbursement.
- To inform and assist healthcare professionals with clinical decisions, on different areas, such as patient empowerment, adherence to therapy, diagnosis, prevention, monitoring, prognosis, treatment and health apps prescriptions.
- To provide good practice guidelines for health apps developers, ensuring a proper app development and fit to the market and local/national ecosystem.

79 WHO 2016 From Innovation to Implementation Report

80 https://mhealth-hub.org/assessment-frameworks

81 https://mhealth-hub.org/health-apps-repositories-in-europe

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The following **steps** can be considered in setting up an assessment framework and evaluation process:

11. Define the scope of the assessment framework
12. Decide on the types of apps to be covered
13. Involve experts
14. Decide on assessment domains and criteria
15. Define workflow for the assessment process
16. Consider regularly updating the assessment framework
17. Funding/business model process to ensure sustainability of the assessment process
18. Interface/Digital health libraries or repositories
19. Ensure adoption by the stakeholders
20. Encourage reflexive learning

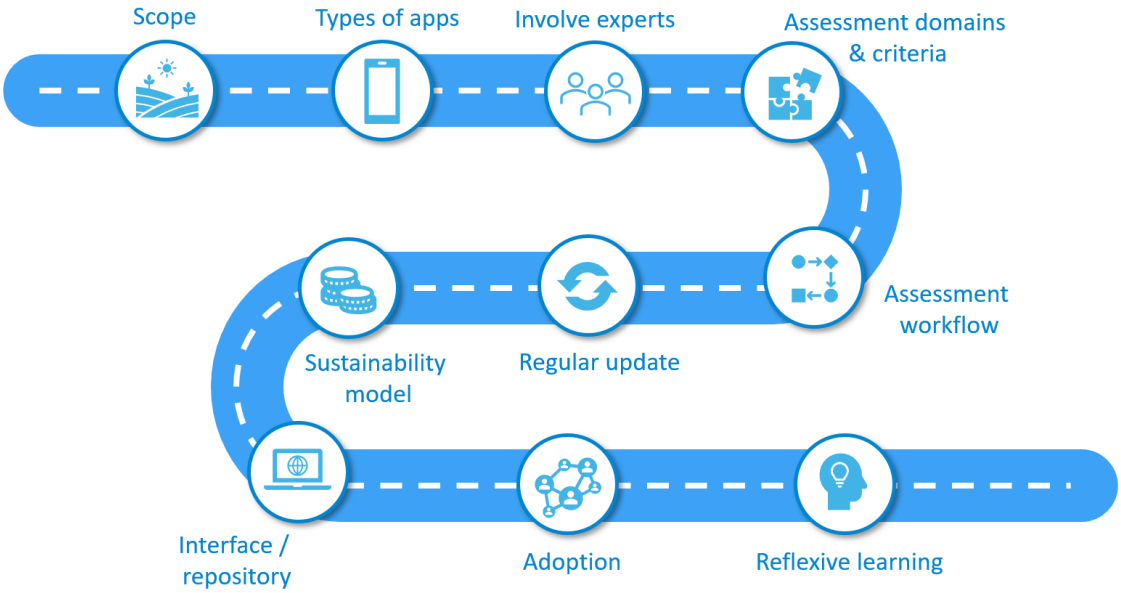

Figure 8. Key steps when setting up a health apps assessment framework and evaluation process

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DEFINE THE SCOPE OF THE ASSESSMENT FRAMEWORK

An assessment framework in the most generic sense provides a set of criteria against which mobile health applications can be evaluated. The purpose of mHealth evaluations can be summarised in the following points:

- To ensure broad, rapid, and sustainable patient and citizen access to digital health innovations and assist with consumer decision-making.
- To provide policymakers and funders/insurers with the necessary information to understand the benefits and comparative value of health apps, to inform policy, funding, and reimbursement.
- To inform and assist healthcare professionals with clinical decisions on areas such as support, patient empowerment, adherence to therapy, diagnosis, prevention, monitoring, treatment, etc. and health apps prescriptions.
- To provide good practice guidelines for health apps developers, ensuring a proper app development and fit to the market and local/national ecosystem.

To achieve these purposes, assessment frameworks are used to:

- Include health apps in Repositories or Health Apps Libraries.
- Set up evaluation and certification processes to enable reimbursement and health apps prescriptions.
- Provide clear guidelines on health apps requirements.

Stakeholders	Benefits/Value propositions	AF modalities	Examples
Citizens Patients Patient organisations Health professionals Healthcare providers	To ensure broad, rapid, effective and sustainable patient and citizen access to and use of digital health innovations and assist with decision-making	Digital Health Apps Libraries	Helsenorge tools iSYS app catalogue Mental health app guide
Policymakers Funders Insurers	To provide policymakers, medical experts and funders/insurers with the necessary information to understand the benefits and comparative value of health apps	Certification processes for reimbursement	mHealth Belgium DiGA directory Digi-HTA recommendations assessments (to inform policy-makers)

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Public health authorities Medical societies	To inform policy, funding, and reimbursement		
Health app developers Industry	To provide good practice guidelines for health apps developers, ensuring proper app development and fit to the market and local/national ecosystem	General guidelines	HAS Good practice guidelines eHealth Suisse recommendations

Table 7. Overview of assessment framework modalities according to stakeholders and value propositions

Key considerations

Decide on the scope and objectives of the assessment framework by:

- Performing a needs assessment.
- Stakeholder involvement and consultation.

A needs assessment is essential to better understand how the local, regional, or national ecosystem might benefit from health apps evaluation processes. Integrating diverse stakeholder perspectives through formal, consistent, and inclusive approaches early in the process is a key to ensure transparency in how the views of all stakeholders are captured and reflected later in the decision-making processes.

Consider questions such as:

- What are the unsatisfied needs or gaps in the ecosystem?
- What are the health and social care concerns that define discussions in the region?
- Who are the main stakeholders to be involved?
- Is there a shared understanding and sense of urgency among the identified key stakeholders about these unsatisfied needs?

Examples

Example 1 (fictional). There is a general concern the region in question has a high proportion of population that cannot properly self-manage their diabetes, leading to increased comorbidity and complications. Therefore, this unmet need could be addressed by setting up a specific mHealth diabetes repository that could include reliable apps for patients. Patient organisations that would like to offer their members reliable condition management apps, could build own repositories.

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Example 2 While ORCHA has been providing MIND with a first selection of quality proved solutions against a set of critical criteria, MIND has then fine-tuned the selection by conducting a number of complementary assessments, often with the direct support of the users leading to a Mind rating of the apps.

The multi-layered digital health assessment combines the ORCHA assessment, MIND test panel reviews, and MIND editorial board consolidated reviews.

"The essence of our success, I think, is the multi-layered concept of co-creation. Because it's a volatile market, we need some kind of stability in guiding that market to the next steps, and that's what we are doing". (Rimmert Brandsma)

(Hub Talk 13.07.21)

Sources: 1 and 2

Example 3. The cooperation with Israel has been a real stress-test for ORCHA given the focus on innovation and the wide range of criteria to be considered and also considering the very specificity of the Israeli market where very few apps are available in Hebrew. (Hub Talk 13.07.21)

Example 4. For mHealthBelgium (medical app assessment framewok in Belgium), it is overall a quality label to show to broad public (patients, citizens, healthcare professionals) which apps fulfil the basic criteria made by national authorities. But on the other hand, it is for the app providers also the unique path to follow to submit their reimbursement file to the payer authorities. see more info on https://mhealthbelgium.be/

DECIDE ON THE TYPES OF APPS TO BE COVERED

The mHealth ecosystem comprises a variety of health apps. While there is no international consensus regarding the classification of health apps, countries consider many dimensions such as medical use cases, technical modalities, MDR classes, policy considerations and others.

Key considerations

- Consider how are health apps legally defined in the country in terms of scope (e.g., digital health apps and/or wellbeing, inclusion in health services, MDR classes, clinical procedures, level of integration with EHRs and other systems).

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- Take into account, according to the level of app complexity included, a flexible approach to the assessment process (e.g., adding more criteria or more assessment steps for more complex or sensitive solutions).
- Consider elements such as the language and other country specific facts. The assessment process might receive world-wide applications or might apply only to the specific language to the national or regional initiative. This might also influence the ways and which providers to consider reaching out to.
- Consider what type of evidence related to the apps is needed for the use or classification of the apps for certain purposes. An app that may have a purely voluntary position in one country may be reimbursed in another country, according to the app type and level of evidence required.

Examples

Most of frameworks are used to assess health apps in general, lifestyle and wellness apps. Few frameworks have been developed for specific use cases. The *MindApps.dk* or *https://www.ggzappwijzer.nl* are dedicated to mental health apps, while *DiaDigital* (App Check) is used to assess diabetes apps and *PneumoDigital* (App Check) for respiratory diseases apps. Some frameworks like *Orcha* or *DTAC* from NHS cover explicitly both health and care apps.

On the other hand, some of them have criteria that can be applied only to apps that are certified as medical devices and have CE certification (e.g. *mHealthBelgium*). The Bertelsmann Stiftung developed the *AppQ* set of quality criteria DiGA that are subject to the scope of the German Medical Devices Act (MPG) or has a comparable approval by a foreign authority for medical devices, e.g. by the Food and Drug Administration.

A special case is constituted by the *APPKri* framework, a comprehensive meta-catalogue of criteria for evaluating health apps designed for patient organisations or other groups that wish to engage in a systematic evaluation of health apps.

To learn more, please go to *Qualitative insights – assessment subject*

INVOLVE EXPERTS

To ensure a proper evaluation, consider involving experts to voice the interests of stakeholders.

Key considerations

- Involve the experts and organisations according to the defined objectives and ensure that all aspects can be correctly addressed and evaluated.
- Consider adding new organisations/stakeholders according to the current needs of the ecosystem and framework.

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Examples

In their framework, Tic Salut Social has extended collaboration with experts from various fields, where physicians, nurses, psychologist, experts in physical education and sports, technical developers, usability experts and data protection experts are taking part in the assessment process.

To learn more, please go to *Qualitative insights – assessors*

DECIDE ON ASSESSMENT DOMAINS AND CRITERIA

For health apps to pass certification processes, they need to fulfil certain criteria. While certain criteria should apply to all frameworks use-cases (e.g., security and privacy), others might depend on the classification of the app type and requirements. The Hub project deliverable D2.1 (Knowledge Tool 1) describes how the different existing frameworks cover these 12 quality domains/criteria (privacy, transparency, safety, reliability, validity, interoperability, technical stability, effectiveness, accessibility, scalability, user experience/scalability, security).

DEFINE THE WORKFLOW FOR THE ASSESSMENT PROCESS

Key considerations

Consider workflows such as:

- Self-assessment performed by the app developers.
- Expert assessment.

In the self-assessment, the developer follows the guidance material and undertakes self-assessment. In the expert assessment, the app submission of the developer is evaluated and decided further on approval or rejection.

Specific phases/blocks of assessment can be defined. Consider phases such as:

- **Initial assessment**. It can take the form of a self-assessment provided by the app developers to assess the eligibility of the app or it can be directly performed by the expert committee.
- **Technical assessment**. The app is assessed against a defined set of criteria.
- **Functional assessment.** The app is being tested by real users from the committee to ensure proper functionality exists.
- **Ethical assessment.** The app meets ethical requirements.

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- **Assessment of clinical benefits** (where appropriate). EBM proofs are obtained, e.g., as a result of a clinical study. The assessment may either include the study or evaluation of its results if it was performed separately.
- **Socio-economic assessment** (where appropriate). Calculations, models, studies in real world demonstrating socio-economic benefits.
- **Feedback process**. Sharing the assessment results with the developers.
- **Assessment result and accreditation process**. The result of the app assessment is summarized in a report and the app may be conferred the specific certification.
- **Re-assessment**. To ensure the app maintains its conformity to the required standards, periodic re-assessments should be performed.

Other important aspects to consider in the assessment process:

- Decide on a qualitative or quantitative assessment model. A quantitative outcome is represented by a general score, while a quantitative assessment is based on a Pass or Fail schema and represented by a quality seal.
- Consider mandatory requirements that an app must fulfil to pass the assessment process.
- Consider requirements related to the technical support and maintenance of the app, which may require availability of trained staff on the side of app providers for a certain period of time.
- Consider optional requirements that are recommended and increase functionality and/or quality to the apps.
- Consider sharing the assessment report with the app development team.
- Consider a semi-automated assessment process where possible.
- Consider having a transparent decision-making process for all stakeholders involved.
- Consider the measures necessary to ensure a robust assessment framework throughout the app's complete lifecycle.

Examples

Several frameworks have a clearly defined assessment process. Most of them yield either a quantitative outcome represented by a general score, or a qualitative outcome, represented by a quality seal or a recognisable vignette.

For *Tic Salut Social*, the accreditation process has three phases that include the review of the application, an initial technical validation together with a functional validation, and a last technical accreditation.

In the *AppCheck* assessment, besides the general process that includes self-assessment and expert assessment, the organization offers the possibility of a teleconference in which all testers can participate.

For *BfArM*, the procedure is designed as a fast track. The core of the procedure is the examination of the manufacturer's information on the required product characteristics, as well

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as the examination of evidence to be provided by the manufacturer for the positive care effects that can be achieved with *DiGA*.

For *mHealthBelgium*, the app assessment framework is a validation pyramid with 3 levels. An app always enters at the lower level, M1, and can climb in hierarchy via M2 to the top level, M3. To be allowed to the next level, the app first need to fulfil all criteria of that level. Every level has its own automated process with predefined flows.

MySNS Selecção assessment process contains three steps. The first and second step are dedicated to the health app owners, to review all the framework requirements needed and fill out the form application to submit the app. In the third step, the applications are evaluated by a group of experts in terms of performance, security and public utility using qualitative scores. If the apps comply with all the evaluation criteria, they obtain the quality seal "Selected" and will be part of the *MySNS Selecção* library available in the website. The apps that need to perform improvements in some criteria, they will acquire the "Pre-Selected" seal.

The *ORCHA Review Process* consists of seven stages described in high detail on the *ORCHA* website. The aim of *ORCHA* scoring is ultimately to reward best practice and highlight poor practice or no compliance. The mechanisms used are designed to ensure that, wherever possible, the score reflects relative performance and properly differentiates between similar apps. The different analysis stages result in a quantitative score based on the answers to each of the questions in the three review domains. During the cooling off period following their Review, the Developer is able to raise any issues or concerns with the Review Team. Finally, *ORCHA* has a feedback mechanism on all supported platforms for end users (professional and none professional) to alert to any inaccuracies or errors.

My Health Apps review consists of two stages. In the first stage, the assessment is performed either by the developer (self-assessment) or by the users or healthcare communities who want to include an app in their repository. In the second stage, background checks are being carried out by *PatientView*.

For *ISYS Score*, apps are included through 4 procedures. The first, and most relevant, is by searching for the 10 best results offered by *Google*, by ICD-10 category (14 categories), which represents a total of 140 Apple Store apps and 140 Google play apps (total 280 Apps captured every December). Those that exceed the inclusion criteria are selected below. The second is on the recommendation of patient associations. Every year, a group of 30-40 patient associations are consulted to make their recommendation. The third is to re-evaluate the top 5 from the previous year. The apps are published in the yearly *iSYS* catalogue.

To learn more, please go to *Qualitative insights – assessment process*

ASSESSMENT FRAMEWORK UPDATE OR MAINTENANCE

Update is key when thinking of ensuring quality.

Key considerations

- Consider reviewing the assessment framework in the light of new regulations and standards.
- Consider refining and/or enriching the framework criteria based on experience and lessons learned.

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Examples

The update frequency varies strongly between AFs. Most of the framework owners aim to update them regularly. For example, iSYS app catalogue is yearly updated since 2014.

Some other recent initiatives, like BfARM from Germany, indicates that the guidance documents will be continuously adapted, supplemented and further developed based on experience gained.

To learn more, please go to *Qualitative insights – year of creation and update frequency*

FUNDING/BUSINESS MODEL PROCESS TO ENSURE SUSTAINABILITY OF THE ASSESSMENT PROCESS

Key considerations

- Evaluation of costs necessary to set up the assessment process: Costs of platform maintenance etc.
- Partnerships.

Depending on the purpose of the evaluation, different sustainability pathways and business models can be considered:

- Public funding
- Perceived fees for assessment and inclusion in the repository, or reimbursement list
  - Layered approach for different types of categories (individuals, SMEs, large companies)
  - Different fees for the different assessment steps
- Yearly fees of apps being included in the repository

Examples

Some companies perceive fees for the assessment and inclusion in the website repository. The fees often vary considerable between initiatives. Several frameworks do not perceive any fee. Some of the frameworks are intended only for self-assessment purposes and are available online.

In the case of *mHealthBelgium*, for example, companies who want to get their quality label and hence be visible on the portal, pay a yearly fee of 1000 euros (25% reduction for those who are member of *Agoria* and/or *beMedTech*). This budget will be used to maintain the platform and is an incentive (at least yearly) for the providers to keep the app info up to date.

To learn more, please go to *Qualitative insights – sustainability/business model*

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INTERFACE/PRESENTING THE ASSESSMENT RESULTS. DIGITAL HEALTH LIBRARIES OR REPOSITORIES

Key considerations

- Technical implementation of the library (hosting, website layout, etc).

When building a repository, consider detailing information on the website about:

- Language and scope. Is it an international initiative, receiving world-wide applications, or is it a national/regional initiative that is language specific?
- Transparency of the assessment process for all stakeholders
- How the repository is updated and maintained
- Information about apps. Help end-users to find best apps for their personal needs, rather than just focusing on assessment criteria. Consider elements such as:
    - Listing app functions.
    - Who is supporting the app, where does the product has more impact and for which population.
- Include search filters to ease the navigation through the repository
- Define a clear process in place for delisting or archiving apps, or alternatively marking apps that no longer fulfil the requirements or may no longer be supported by the developer(s) or existing platforms.

Examples

So far, 22 repositories have been identified by the *European mHealth Hub*. There is a high diversity in their features:

Repository object: most of the repositories have their focus in the "apps", in a generic or thematic way (mental health, diabetes, respiratory diseases, Parkinson). The most recent ones have a broader scope, including also other digital tools.

Language: Only a minority of the non-English speaking repositories include some information in English. The others tend to develop its work mainly for national or regional target audiences.

Number of apps included: several repositories do not include such data. There is a big disparity in the number of apps included, with some repositories including less than 50 apps, and a few others that clearly exceed that figure.

How can one app be included in the repository: the repositories that are based on a stablished and transparent assessment process -and also in some cases a quality seal-can be seen as having a more solid background.

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Apps scoring and ranking: in some repositories these resources are used to make the assessment information more understandable or appealing for the target audiences; however, to be truly effective, these elements need to be accompanied of enough transparency.

Search browser and filters: some repositories have gone beyond a simple list of the apps they include, enriching it with elements such as a search browser or different filters that makes the repository tool more user-friendly, especially when the number of apps is high.

To learn more, please go the section *Health apps repositories*.

ENSURE ADOPTION BY STAKEHOLDERS

Understand the needs of the stakeholders and find appropriate ways to address them. Identify other end-users of the AF to spread the awareness and identify further gaps and needs that the health apps could cover.

Key considerations

- Dissemination and communication aspects
- Trainings with healthcare organisations and healthcare professionals

Examples

Several initiatives can be mentioned, that address not only the appropriate design of a framework, but also how it is adopted.

In UK, Digital Healthy Schools, an initiative powered by Orcha, are empowering young people for a positive use of health apps (46.5% increase after participation in the programme).

Another interesting example is the Nordic Interoperability Project, where the interest on adoption is clear:

"It's really important when starting looking at these kinds of frameworks that unlocking the power of digital health is not about finding the right standard and how to do the accreditation, it's more about finding a system where you also focus on the implementation and activation of digital health. We don't need a lot of quality assured digital health solutions; we need a lot of quality assured digital health solutions in the right hands – in the hands of the healthcare workers and of the individuals." (Anders Tunold-Hanssen).

Sources: Hub Talk 13.07.21; ; news

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ENCOURAGE REFLEXIVE LEARNING

Key considerations

- One of the main barriers to mHealth implementation is represented by a lack of collaboration between key stakeholders. Consider encouraging reflexive learning, what worked, what didn't, and adapting the process according to the lessons learned

Examples

The twinning activities for knowledge exchange and shared learning constitutes a very good opportunity for the AFs.

Recently, the frameworks *AppSaludable* from Andalusia (Spain) and *My SNS Seleção* (SPMS, Portugal), have developed a twinning under *Digital Health Europe* project.

These Hub orientations were presented and described at the Hub Talk 17.06.21 (from beginning to minute 16)

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4.9 27 aspects in which health apps assessment frameworks could be enriched

On the basis of the extensive work done by the Hub on health apps assessment frameworks, the following ones are concrete areas suggested to AFs owners to further develop the different assessment domains. (Infographic and table)

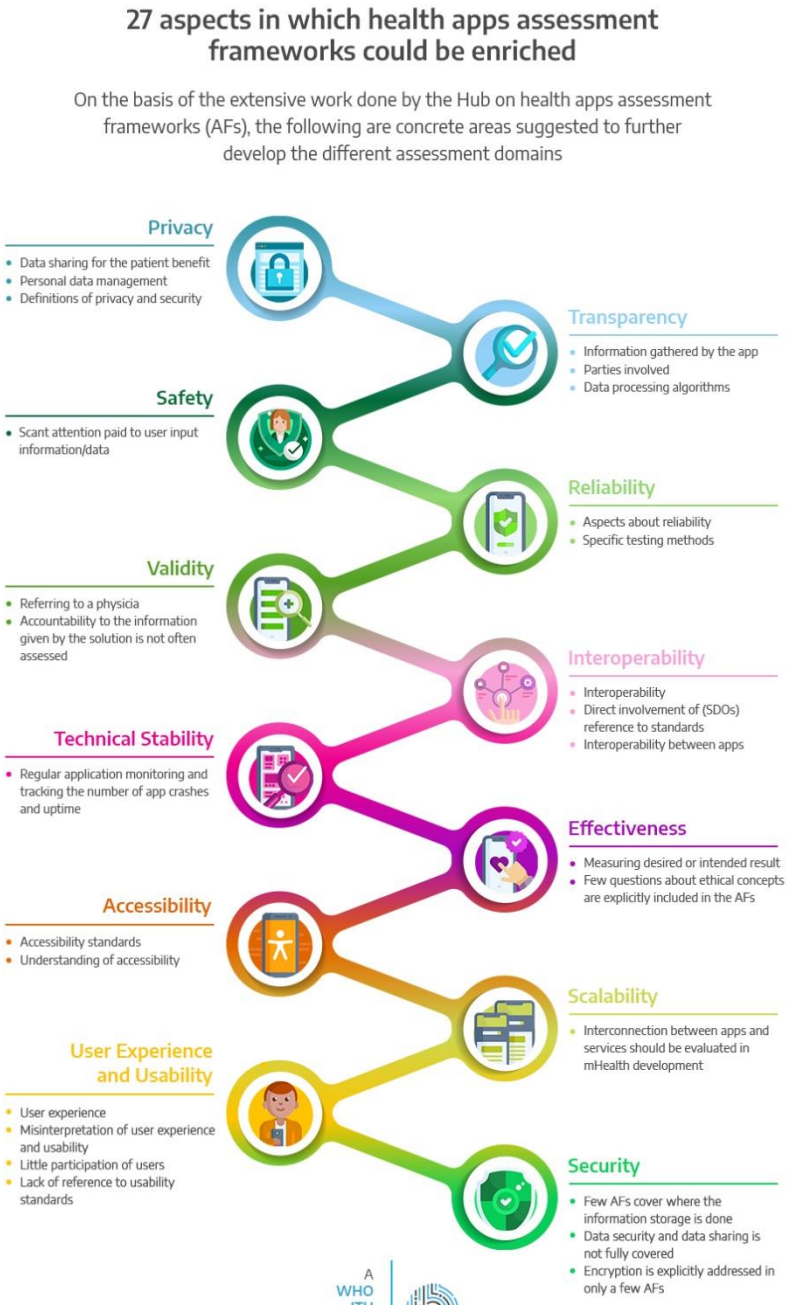

Figure 9. Infographic

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Assessment domain	Aspect
PRIVACY 	1. Scant attention paid to data sharing for the patient benefit. Well-defined data sharing for the patient benefit must be made available even across borders and should be requested by the AFs. 2. Lack of information about personal data management. Little attention is paid by the AFs on how the personal data are managed in terms of access, retention policy and transmission methods. Additionally, analytics applied to the patients' data should be disclosed and assessed. 3. Definitions of privacy and security overlap or are missing. Definitions of the assessment domains of privacy and security are sometimes mixed and not addressed separately. Concise and clear definitions of privacy and security in AFs as well as for the user are missing.
TRANSPARENCY 	4. Information gathered by the app is often not fully disclosed to the user. Many AFs do not fully cover the question of what information is handed over to the app, which interests are included by stakeholders and how algorithmic app components deal with the available information. A clear and concise description of collected and processed information for the user is missing. 5. Lack of information about parties involved. A clear statement about the stakeholders and their roles (development, financing, etc.) involved in a mHealth application is often missing. 6. Information about data processing algorithms is often not provided. Basic but concise information about data processing algorithms is not perceptible for all the stakeholders. Most AFs available today do not require this.
SAFETY 	7. Scant attention paid to user input information/data. User input information has great impact in diagnosis and monitoring, and for that reason specific attention to this issue needs to be paid in the AFs. Safety of users/patients/citizens depends also on the validity of their own inputs and on ways an app or mHealth solution can validate and detect problems and deviations of the data collected. Reporting and alerting these cases to health

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	professionals is also an important measure of safety that relates to user input information.
RELIABILITY 	8. Few specific aspects about reliability are assessed. Key questions might be used to complement assessment of reliability, i.e.: • Are recurrent bugs and security bugs in the software documented? • Can the terms and conditions or use-based warnings be documented? If measurements are collected, their metrological characteristics must be transparent so that their levels of precision and accuracy can be understood. Precision should be appropriate for the expected use of the product. 9. Specific testing methods for reliability are missing. Reliability assessment, among others, uses mostly generic terms and questions. It would be fundamental to also evaluate if specific testing is done to verify reliable mHealth solutions. This would ensure proof and confidence in the solutions.
VALIDITY 	10. Referring to a physician is not a common element of assessment. To assess if an app or mHealth solution explicitly informs the users to refer to their physician is an important feature. Refer to a physician can provide the necessary alert to users depending solely on the information a solution provides. This feature complements the necessary and common verifications of the information provided by the mHealth solution. 11. Accountability to the information given by the solution is not often assessed. Most AFs do not evaluate if an mHealth solution provides accountability to the information given by the solution or to the sources of information. Accountability is central to discussions related to problems in the public sector, such as health, and provides security and safety for the users.
INTEROPERABILITY 	12. Interoperability is not part of the majority of AFs. Interoperability as a topic as such is not included in most of the AFs. The AFs tend to leave the term interoperability as a side note and do not discuss means/requirements to ensure interoperability as such. 13. Lack of direct involvement of Standards Development Organisations (SDOs) and reference to standards.

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	The AFs that addressed the subject of interoperability did not cover it in sufficient detail. They do not reference specific IT standards. Exceptions are frameworks that originate from SDOs like the HL7 functional framework for health apps. 14. Poor contribution to the goal of interoperability between apps. The AFs do not ask that health apps disclose the used data models and services to facilitate interfaces with the app using inter process communication capabilities provided by the operating system. A communication between apps directly on the users' devices is therefore not possible.
TECHNICAL STABILITY 	15. Little mention is made of regular application monitoring and tracking the number of app crashes and uptime. Frequently asked questions in AFs are about the mechanism of error reporting from the user side, documenting and tracking identified errors, and ensuring they are corrected. There is rarely a mention of regular app monitoring by the tech team. A simple example of how to resolve this gap is asking if "the app produces errors log or actions monitoring in an external system" (i.e., *Tic Salut Social*). A more detailed and improved question would be like this one asked by NHS Digital: "Do you proactively monitor running of systems and system components to automatically identify faults and technical issues? Describe your monitoring processes and procedures." There is almost no mention of the tracking number of app crashes and application uptime, which is important not only as an indicator of technical stability but as an important factor in the user experience.
EFFECTIVENESS 	16. Measuring desired or intended result (e.g., improved health outcome) is covered only in a few AFs. AFs should capture if the application can measure a desired or intended result in everyday use and particular environments. Some AFs do ask questions like if the app sets goals for users or allows them to set goals for themselves; if goals achievement is tracked; if there is a visibility of progress, so some results are measured. There is a gap in measuring results by the app provider, controlling if data generated and recorded are accurate, if it is relevant to the range of values expected in the target population, and if it is possible to detect clinically relevant changes or responses. Also, there is a gap in demonstrating relevant outcomes of application (e.g., behavioural or condition-related user outcomes such as reduction in smoking or improvement in condition management, evidence of positive behavioural

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	change, user satisfaction), and presenting comparative data (e.g., relevant outcomes in a control group, use of historical controls, routinely collected data) by the app provider. Note: example for relevant outcomes and present comparative data taken from Evidence Standards Framework for Digital Health Technologies: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies 17. Few questions about ethical concepts are explicitly included in the AFs. While assessing AFs for effectiveness criteria, specifically if the framework can capture the app's applicability by distinguishing different subgroups of users (e.g., demographics, age, gender, health literacy, medical condition, health status), it has been observed that most AFs do not include questions concerning to ethical concepts. When they exist, questions regarding ethical concepts are spread through different assessment domains.
ACCESSIBILITY 	18. Very limited recommendations on accessibility standards. Most of the AFs do not explicitly recommend the web content accessibility guidelines (WCAG 2.1 standard), which makes it difficult to improve the accessibility of mobile health for general population. 19. Limited understanding of accessibility. Many AFs consider accessibility as just secondary functionalities of the user interface, such as font size and contrast, while other aspects, such as an in-depth analysis of the populations needs in terms of disabilities (e.g., percentage of population who is colour blind or have sight disabilities), are non-existing.
SCALABILITY 	20. Interconnection between apps and services should be evaluated in mHealth development. There is a gap in assessing whether an mHealth solution can interconnect to several services and platforms. If such assessment is done, there is a benefit for the developer to provide its service to a wider audience, leveraging and expanding a solution for the wellbeing of its users. One recommendation that can arise from this is to allow development of the mHealth solution to be independent and parallel to the interconnection mechanisms.
USER EXPERIENCE / USABILITY	21. Lack of reference to usability standards. Little mention or recommendations on usability standards (e.g., ISO 9241-210:2019), which makes it difficult to

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	improve the usability of mobile health applications for the general population. 22. User experience is generally absent or only mentioned as a side note. Most AFs do not consider the user experience as a central part of the adoption and scalability of mobile health. 23. General misinterpretation of user experience and usability. Measures of effectiveness, efficiency and satisfaction are not generally among the recommendation for evaluating mobile health applications. 24. Little participation of users in the design and evaluation of mobile health. There is a general understanding among the AFs that users, if involved, should be only part of the late test of the applications. Inputs in the design stage are seldom, neither the space for decision-making input.
SECURITY 	25. Few AFs cover where the information storage is done. Concerns about jurisdiction of where the data is stored can have an impact also on other domains, such as privacy. Having different rules in different geographies should be an element of assessment. Also, this can impact models of monetization for the mHealth solution developers that can end up not being transparent to the user. 26. Data security and data sharing is not fully covered. Data security is fundamental for trusted and secure use of mHealth. Across the several AFs analysed, most of them are concerned about data security, mostly related to privacy, and data sharing, mostly related to third party involvement. Nevertheless, the lack of ubiquitous focus of these two security aspects can be a barrier for a universal assessment for mHealth, and so there is a need to overcome this issue. 27. Encryption is explicitly addressed in only a few AFs. The main goal of encryption is to prevent unauthorized parties from reading private, confidential or sensitive data. To this end there is a reduced number of AFs that address this particular subject explicitly. There is a common procedure in the AFs to either recommend or assess security in transmission of data and storage of data, but there is a lack of explicitly recommend a encryption method. Furthermore, there are some AFs that link their rules and criteria to the GDPR regulation that also recommends encryption for the purpose of dealing with personal data but it misses a specific solution. The

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	recommendation resulting from this analysis is for an AF to assess if a specific method of encryption is in use.

Table 8. 27 aspects in which health apps assessment frameworks could be enriched

Web version: https://mhealth-hub.org/27-aspects-in-which-health-apps-assessment-frameworks-could-be-enriched

4.10 Learnings from the existing health apps assessment frameworks: selection of innovative insights

On the basis of the extensive work done by the Hub on health apps assessment frameworks, below are summarized a selection of innovative insights that constitute learnings from their development, and that can be helpful for other AFs owners or quality planners.

Assessment domain	Innovative insight
PRIVACY 	Europe faces a lot of illnesses based on society behaviour. The demand for mHealth based solutions and applications is rising. These are developed either by large international companies or smaller predominantly local companies with new ideas for health services. Focus of both is usually to address an international market with an emphasis on scalability. By stating clear rules of how patient data is handled (GDPR), the trust in mHealth apps will be increased for European citizens and the use of mobile apps might increase. Creating a *trustworthy environment* is the key to wider adoption of mHealth solutions and apps by patients and medical professionals. This adoption supports decentralisation of healthcare and further promotes emerging mHealth and telemedicine solutions. Implementation of such solutions reduces costs and inflow of patients to hospitals potentially leading to a higher standard of care. One way of achieving this is for the assessment frameworks (AFs) to focus on *how the personal data are managed in terms of access, retention policy and transmission methods.*
TRANSPARENCY 	Transparency for mobile Health applications requires information on several aspects like benefits and effects of such tools, as well as the actual use and possible harms. Based on the short development cycles, a transparency evaluation may partially only rely on data provided by the manufacturer.

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	One of the main aspects of transparency is the *accurate information about the way an application handles, transmits, stores and secures user related data*. This aspect also includes sharing of data with third parties. As transparency is directly linked to the aspects of privacy, safety and security, *examples for the secondary use of data, or the connection to open data platforms* are of special interest. Creating a transparent approach should include full information about the way data is handled, transferred and stored. One way to do so maybe the *usability of transparency enhancing tools*, which are specifically designed to help users to improve their privacy. Transparency tools may also aim to check health-related data, like prescribed medicine or given diagnoses.
SAFETY 	Safety is regarded as a way to safeguard the user of the mHealth solution. For this end almost ¾ of the analysed AFs had this into consideration in one way or another. Most commonly, content quality that provides health benefit for users, is the issue more relevant for the larger majority of frameworks. Claiming a health benefit entails having carried out a benefit risk analysis. Health risks are to be as low as reasonably possible and health benefits are to outweigh health risks to provide users with a degree of safety. An important aspect of safety for users of the mHealth solution is the capacity for a citizen/patient to communicate with a health professional, either by design or by default of the solution. Meaning that if something is wrong with the usage or with the user of the mHealth solution a procedure can be in place to automatically communicate such misuse, or problem, or on demand by its user. As an example, this communication is mostly used by monitoring apps for chronic or prolonged diseases. As a consequence of the mentioned above, *user input information safety* is one criterion that is seldom present, and can be considered an innovative example for the AFs. As an example, *DEKRA* Certification - *Medappcare* framework addresses this issue. The objective can be to assess if an mHealth solution has systems in place to verify or evaluate user input information and report if problems are detected.
RELIABILITY 	As one of the least captured assessment domains, second to Scalability, Reliability assessment examples can provide an innovative aspect to AFs. Reliability focuses primarily on consistency and stability of results. Other aspects, collected from the analysis, are the *assessment of errors* and *how everything gets logged or documented*. To this end there is one example (France Good Practices Guidelines) that assesses failure rates, measurement error rates, and hardware risks of all types. The *data* should be also *evaluated and documented*, which is a big focus in one instance that can be a good example to follow in other AFs. This is a critical domain because the accuracy of data collected may

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	vary between the products available on the market and their intended uses. Users should be aware of the precision and reproducibility of data measured for the intended use. *Testing* is also an important part of reliability, but even fewer frameworks address the issue. To this issue there is space to expand reliability assessment by means of introducing assessment of testing methods. Such a case is present in one of the AF (ISO/TS 82304-2).
VALIDITY 	Medical backing and valid information are of great concern when implementing mHealth solutions. This domain is assessed by more than half of the frameworks. It is important to have in mind two main paths to evaluate validity that are expressed in, for example, *AppSaludable* framework: the *validity in terms of where the information is gathered and supports the content of the app*, and the *validity in terms of accountability to the information that supports the app*. Both aspects are of great importance and should be considered. Some assessment frameworks go even further to assess the *level of liabilities* for the information provided. Most of the frameworks only consider one of the paths (the source and proof of information) and thus there is an opportunity to improve frameworks in the validity domain. Also, what stands out from all the frameworks that address this domain is the fact that only a few are concerned with very clearly indicate the user to *refer to their physician*.
INTEROPERABILITY 	Europe comprises of different countries each having its own health IT infrastructure and often employing different healthcare strategies. By implementing standardized interfaces (based on international harmonized communications standards) the likelihood of a wider-scale adaptation of an app in multiple EU countries increases. mHealth apps can be included into existing systems-of-systems by respecting common interfaces to share data. Hence, such mHealth apps address a bigger market (EU/international) compared to applications that establish proprietary data solutions and services without interoperable link to the overall IT infrastructure/system. The AFs could include *references to specific harmonized international IT standards*. Furthermore, requirements could focus on *disclosing the used data models and service specifications* to facilitate interfaces with the mHealth app using inter process communication capabilities provided by the operating system. This step would facilitate direct communication between apps on the users' devices.
TECHNICAL STABILITY	As it is previously stated, it is important to ensure that the app can maintain its level of performance in technically demanding events like a sudden increase in the number of users, the simultaneous connection of all users, a sudden increase in the

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	amount of data, and everyday events like an interruption of the internet connection. To ensure apps' level of performance in those events, app providers need to do performance testing. Some AFs do ask about testing, but with a focus on end-user testing. Although they do not ask questions about testing while assessing applications, Tic Salut Social in their Developer's handbook describes necessary *tests* that should be carried out to ensure that the software complies with the identified needs and with the design. • *Unit tests* are those which evaluate the functionality of a method or a function for example, in isolation from the rest of the system. • *Integration tests* consist of investigating how two or more elements which have previously been subject to unit tests work together. • *Stress tests* focus on the software's performance when it is tested to the limit, to see how long it manages to work normally and what happens when this threshold is exceeded. • *Penetration tests* are tests involving a simulated malicious attack by someone using the latest techniques to violate the app's security to extract its data, corrupt its operation, etc. This description can be used for improving questions about testing in the technical stability domain.
EFFECTIVENESS 	As a result of assessing AFs, it is pointed out that more than 80% of reviewed frameworks can capture if the assessed app is claiming to have health benefits. Most of those frameworks capture what health benefits the assessed app is claiming to have and if is there evidence about claimed benefits. Only a few AFs are not focused only on *health benefits* but also ask about *other types of benefits* – economic, behavioral, psychological, social, etc. An innovative example that has to be mentioned is a benefits question that includes the concept of ethics, asked by CEN/ISO: "Is evidence available of a positive effect of the health app on health inequalities, access to care for hard-to-reach populations or eliminating discrimination?". When building or upgrading AF, it is recommended to think about including other types of benefits in addition to health benefits. Questions asked about the other types of benefits can be formed the same as questions asked about health benefits. *Capturing health risks and side effects* of mobile applications is very important for patient safety. This criterion can be assessed under effectiveness, patient safety, clinical safety, device safety, quality, risks, but it is important that it is assessed. A lot of AFs ask a question about if is there a health risk or a side effect of mobile application, next question is usually if this risk or side effect can be captured. These questions can be expanded with a list of all possible risks and side effects mobile application can cause, and the question is if information on

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	potential risks and side effects is available to the patient using the application. Improvement can be made on *capturing a methodology used to identify possible risks or side effects*. Also, AFs could ask about *measures* that have been *put in place to prevent a recurrence of any reported events.*
ACCESSIBILITY 	*Use of web content accessibility guidelines* (WCAG 2.0) that apply to mobile web content, mobile web apps, native apps, and hybrid apps using web components inside native apps. For instance, *mobile accessibility considerations* must be related to the *four accessibility principles: (1) perceivable, (2) operable, (3) understandable and (4) robust.* • Perceivable incorporate information about the screen size, zoom/magnification and contrast. • Operable refers to control of touchscreen devices, gestures, device manipulation and placement of buttons. • Understandable refers to screen orientation, consistent layout, scroll, grouping elements, actionable elements and customization of screen and gestures. • Robust addresses data entry methods such as virtual keyboard and platform characteristics. There are also examples of *techniques that apply to mobile applications*, such as text alternatives, navigation, predictability and compatibility. See French *Haute Autorité de Santé* "Good Practice Guidelines" (p. 40) and UK NHS Digital Assessment Questionnaire v2.1 (p. 34-35) for a short guidance.
SCALABILITY 	Scalability, as the least captured assessment domain, can be the one to look for to expansion the AF development. This domain is synonymous to growth and interconnection. Common platforms often limit the way applications can communicate with each other to ensure stability of the overall platform. Where the domain is captured, extensive guidelines exist to apply *interconnection between services*, such an example can be found in *PCHA's Continua Design Guidelines*. These design guidelines are focused on enabling the interoperable exchange of information across a Services Interface that can be applied for several different use cases, including uploading of measurement data, completing questionnaires, and executing commands. Another benefit of including Scalability, from the example of the PAS 277, is to include *assessment of compatibility of apps with different platform configurations*. This in turn will have a trickledown effect to assess ways that information collected or used by the app may be reused, under appropriate privacy controls. Also, a possible design feature would be functionality that is dependent upon the underlying platform, and so might need to be changed when the app is supported on a different platform, should be designed as a separate component and that can be replaced without affecting the rest of the app code.

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USER EXPERIENCE / USABILITY	*Use of* international standard *ISO 9241-210:2019* (Ergonomics of human-system interaction — *Human-centred design for interactive systems*) to assess the usability of mobile health applications. In particular, to measure the effectiveness, efficiency and satisfaction of each mobile health application. For instance: • how usability relates to the purpose and use of the product, system or service (e.g., size, number of users, relationship with other systems, safety or health issues, accessibility, specialist application, extreme environments). • The levels of the various types of risk that can result from poor usability (e.g., financial, poor product differentiation, safety, required level of usability, acceptance, user experience). • The nature of the development environment (e.g., size of project, time to market, range of technologies, internal or external project, type of contract). • Aspects related to timing and resources, where extra communication and discussion to identify and resolve usability issues early in the project will afford significant savings at later stages when changes are, inevitably, more costly. In addition, see French *Haute Autorité de Santé* "Good Practice Guidelines" (p. 39-41) and UK NHS Digital Assessment Questionnaire v2.1 (p. 34-35) as a guidance.
SECURITY 	Security, with more than 80% observance, is one of the most predominant domains in the analysed AFs. Security can range from security of data in the mHealth solution, cryptographic communications, protocols, network issues, and more. These are common traits of all the frameworks that address security. Security of user's data, either when logging or sharing it, is the most common assessment. Nevertheless, some important details are not so common but equally important. One of such details, from ISO/TS 82304-2, is the assessment of specifically assessing *if data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, is processed* by the mHealth solution, or app. Also, a good approach identified in the assessment is the usage of very specific criteria from some assessment frameworks. In the example of the France Good Practices Guidelines, *threat analysis* is mentioned and an *assessment of security by design and by default* is made. The specificity goes further with the evaluation of the protection provided through a robust encryption protocol using state-of-the-art cipher suites, such as TLS. Specificity is hard to achieve and may lead to extensive frameworks, but it ensures quality criteria needed for health solutions.

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Table 9. Learnings from the existing health apps assessment frameworks: selection of innovative insights

Web version: https://mhealth-hub.org/innovative-insights

4.11 Exploring commonalities and mutual recognition across health apps assessment frameworks in Europe

The fact of having identified at least 24 health apps assessment frameworks and 22 repositories in Europe, is a clear indicator of the large heterogeneity in this field, related to the purpose and target audience, level of comprehensiveness, depth, or format of each AF.

This diversity has clear consequences on the adoption of mHealth. On one hand, from the supplier side, the companies and developers find important hurdles to deploy a global strategy when it comes to quality assessment processes, with some of them considered as very time-consuming; on the other hand, health systems and professionals show interest in the health apps, but the great number of apps in the market, and the lack of a single system to evaluate them might have a negative impact on the levels of usage, trust adoption and prescription.

Even the main purpose of each AF is not always clear and known. On the Hub Talk on 17.06.21, with 71 attendees, participants were asked about this question. In the figure below, several ideas arise: to have tangible elements, like a repository or a quality label; to create trust or raise awareness (among population or health professionals); and also, but still in a lower frequency, responses like regulation or road towards reimbursement. This type of knowledge is crucial if Europe wants to move towards mutual recognition: which pathways are following each AF? At which level? Alternatively, some participants suggested standardisation as an interesting alternative to this mutual recognition perspective.

For AF owners: Which purpose are you using your assessment framework for?

Figure 10. Which purpose are you using your AF for? (Hub Talk 17.06.2021)

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During the Hub Talk held on 17 June 2021, 90% of respondents considered that working towards mutual recognition between health apps AFs in Europe was 'very important' or 'important'. Only three people gave low importance to this issue.

In your opinion, how important is to move forward mutual recognition between existing health apps assessment frameworks in Europe?

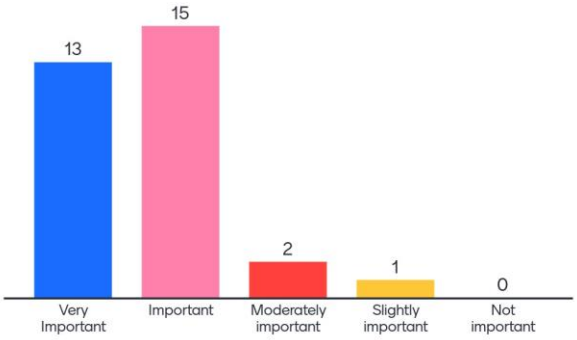

Figure 11. Importance of mutual recognition for the participants in Hub Talk 17.06.21

Besides that, the ways of moving forward the goal of mutual recognition between AFs were explored through a question in *Mentimeter* (see Figure **11**).

Could you suggest effective ways of moving forward the goal of mutual recognition between existing health apps assessment frameworks in Europe?

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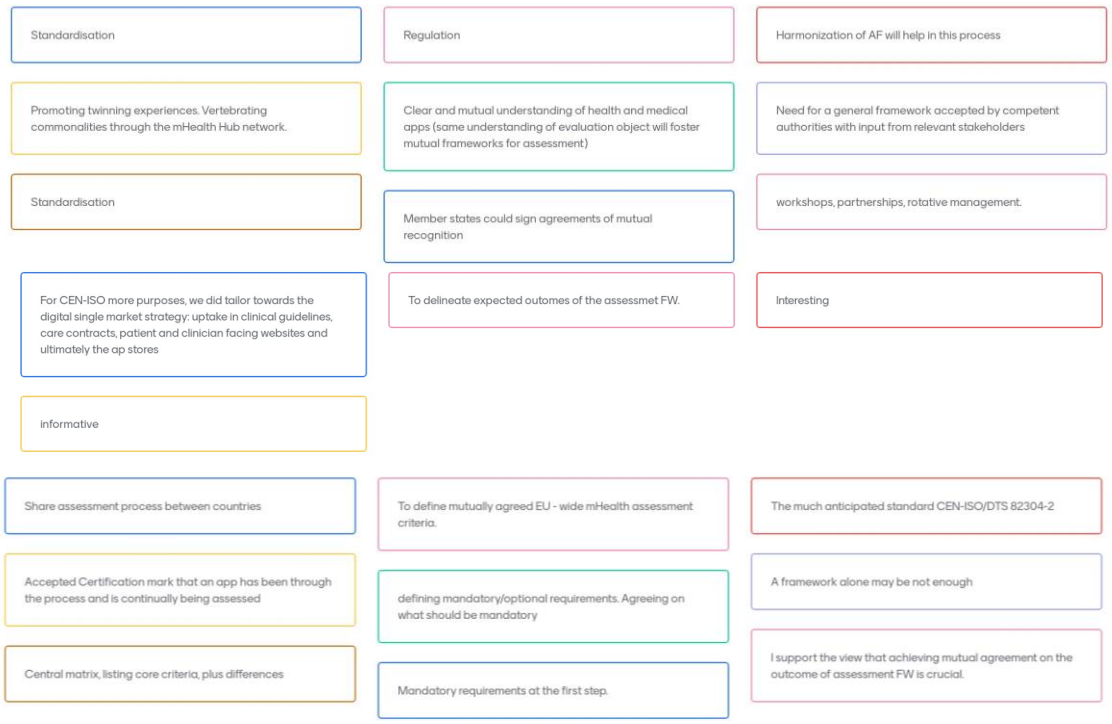

Figure 12. Responses to the question about effective ways of moving forward mutual recognition

According to the responses, the audience pointed in three different directions:

- *Communication, knowledge exchange and collaboration between AFs*

  This block can be shaped in various ways: agreements of mutual recognition, twinnings, workshops, partnerships, network of knowledge, etc.

  Another key idea was the need to understand clearly the evaluation objects and evaluation outcomes of each AF.

- *Mandatory requirements, core criteria or a general framework*

  This block did not receive a lot of responses; however, it refers to the convenience of differentiating between a few mandatory requirements for all the AFs, and optional ones. The key point here is how to reach an agreement on what is mandatory. Also, to determine the added value, a complex aspect because meeting the needs of all the stakeholders involved in the AFs is not an easy task.

- *Regulation and standardisation*

  The recent initiative ISO-82304-2 was highlighted by different participants, as an opportunity to move forward the digital single market. It was also mentioned the recent development of an adaptation of the standard for the Dutch Ministry of Health. Some key aspects in the adoption of this standard will be its uptake in clinical guidelines, care contracts, and presence in websites and app stores.

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At this point, it is also interesting to highlight the intervention from Anders Tunold-Hanssen in another Hub Talk (13.07.21), where he reinforced the importance of a common framework (or at least a big enough framework)- to make digital health investments viable for industry players:

> *"It's not just about looking at digital health solutions from the healthcare perspective (to have a good app), but also to look at it from the industry perspective. We have to give sufficient market place for these solutions to have a business model that gives them sustainability. It is not enough just to be used in a small region or one hospital, then it does not take long before it disappears. We have to give enough market place to make it sustainable, and we are trying that for the Nordic Digital Health and Medication Platform, for regulating an unregulated market to assist the citizens and the health ecosystem, and build a one common Nordic home market for the health app industry*" (Hub Talk 13.07.21 minutes 47-49)

Based on the described context, and responding to EC's interest on this issue, the European mHealth Hub has developed in the next pages the first steps of an approach for commonalities and mutual recognition graded in three intensity levels, according to the outcomes of criteria coverage shown in Annex 4. Results visualization: criteria coverage within each domain by the analysed frameworks.

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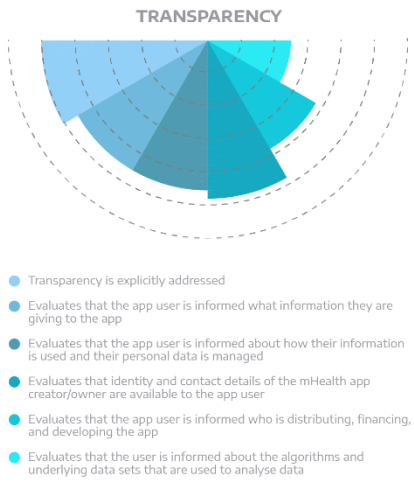
12 assessment domains • Privacy • Transparency • Safety • Reliability • Validity • Interoperability • Technical stability • Effectiveness • Accessibility • Scalability • User experience / usability • Security	5-8 criteria analysed per domain (See Table **3**. Evaluation domains and criteria) Visualizations (See Annex 4. Results visualization: criteria coverage within each domain by the analysed frameworks) 	Intensity **level 1** **>83%** *Criteria considered at least in 20 out of 24 AF* Intensity **level 2** **66%-83%** *Criteria considered in 16-19 out of 24 AF* Intensity **level 3** **50%-66%** *Criteria considered in 12-15 out of 24 AF*

Table 10. Criteria coverage by the AFs and intensity levels as a way to explore commonalities and mutual recognition across them

Note: this exploration of commonalities and mutual recognition was presented and described at the Hub Talk 17.06.21 (from minute 16 to minute 36)

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The first of these intensity levels could be considered or adopted by countries or regions as common grounds when building their own AF. The additional levels could be added on top of that, based on specific national or regional needs. This most intense level could also help as guidance or starting point for mutual recognition across existing AFs.

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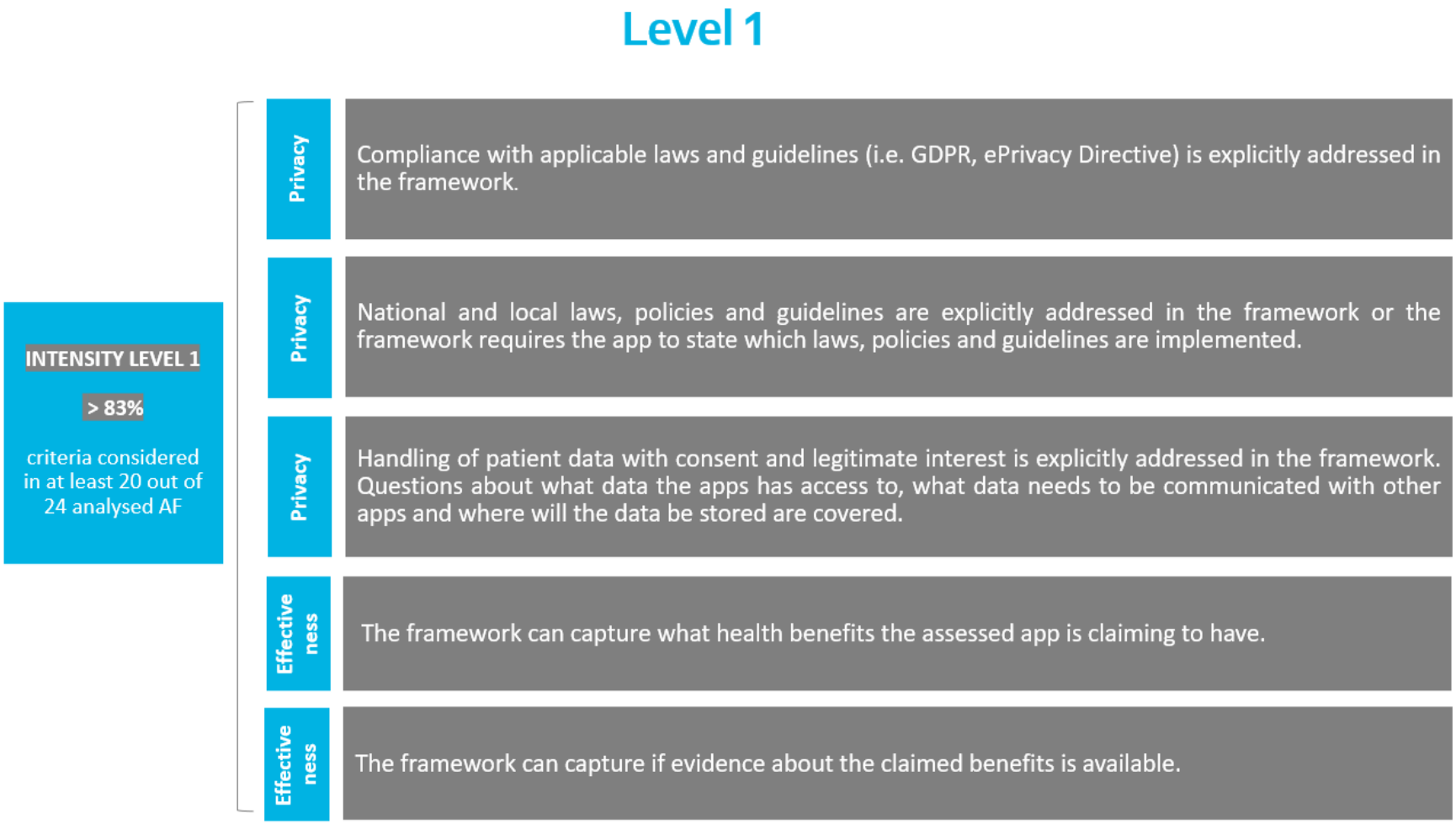

Figure 13. Criteria coverage – intensity level 1

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PRIVACY

Compliance with applicable laws and guidelines (i.e., General Data Protection Regulation (GDPR), ePrivacy Directive) is explicitly addressed in the framework.

The majority of the reviewed AFs concern themselves with compliance to applicable international laws and guidelines (i.e., GDPR, ePrivacy Directive). In recent years, there is a fundamental shift, recognising that a "consent of a user" is needed. This is driven most notably by legal requirements such as the GDPR. The GDPR enforced by the EU created a significant milestone in addressing privacy issues. This can be viewed as a successful effort of law and policymakers, focused to ensure the privacy of personal health data.

The frameworks often reference and highlight criteria necessary to achieve compliance with the GDPR (e.g., ISO 82304-2, mHealth Belgium, AppKRI, AppQ, My Health Apps). Alternatively, measures for privacy protection according to current legislation (AppsEstrategia, DAQ) or the Code of Conduct and Privacy for Mobile Health Applications (My SNS) are referenced.

Most AFs pay less attention to explicitly addressing how personal data are managed in terms of access, retention policy and transmission methods. Many AFs address these points by referencing the current legislation or questions about whether the application has been developed following the principles of privacy by design and privacy by default (Code of Conduct on Privacy and mHealth apps).

National and local laws, policies and guidelines are explicitly addressed in the framework or the framework requires the app to state which laws, policies and guidelines are implemented.

National and regional laws in EU Member States reflect requirements of EU regulations, thereby enabling harmonization of legal requirements between Member States.

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The majority of the AFs take into account the national requirements given by national legislation such as medical device regulations, regulations for professions, data privacy laws, see for example the "What is a good health app" AF and the *BfARM* guidance AF. These AFs ask developers to state the regulatory and legal compliance requirements that the mHealth solution must meet.

In addition to the laws, AFs also sometimes specify requirements and provide guidelines for implementing best-practice approaches, for example, the *cMHAFF* AF. This additional information allows users to better assess the degree to which a product meets the relevant criteria. Furthermore, operating licences or certifications awarded by an institution such as International Organization for Standardization (ISO 82304-2), *Agencia Española de Medicamentos y Productos Sanitarios* (TICSS), Federal Authentication Service (mHealth Belgium) or companies (*ORCHA*) are sometimes referenced in the AFs.

Handling of patient data with consent and legitimate interest is explicitly addressed in the framework. Questions about what data the apps have access to, what data needs to be communicated with other apps and where will the data be stored are covered.

Patient data, as well as personal data in general, is a commodity of which the population is becoming more and more aware. Clear criteria and guidelines are necessary, which require the manufacturers and stakeholders of a product to meet clear conditions regarding the processing of handling personal data. Many mHealth applications can be used free of charge. However, concerns arise about products that track users and collect data about their behaviour (e.g., interaction with the app, frequency of use).

The majority of the AFs address this topic directly by inquiring about whether the health App clearly describes the terms and conditions of recorded personal data and if informed consent is granted by users.

Further questions in the AFs focus on whether the health app informs about the kind of user's data to be collected and the reason, about the access policies and data treatment, and possible commercial agreements with third parties (e.g., ISO 82304-2, Apps Estrategia, appKRI). Data protection concerns arise if collected data is provided to third parties. Information about how and to what extent analytics and associate services are allowed to process such information is addressed by some AFs.

As part of the GDPR, these requirements are included in the criteria catalogue by the majority of the AFs (> 80 percent).

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EFFECTIVENESS

The framework can capture what health benefits the assessed app is claiming to have.

Almost all analysed AFs ask what the health benefits of the app are, but they ask it as a part of different domains (e.g., effectiveness, technical assessment, evidence of outcomes, medical aspects, quality and safety, content validity, appropriateness, content, and information sources).

Some AFs ask precise and direct questions about health benefits, for example, "What are the main benefits or advantages of this particular health app? What health benefits does this health app bring to patients and the public?" (*My Health Apps*). In addition to such a question, a description of claimed clinical benefits and the timeframe for success can be required (NHS digital).

On the other hand, there are a lot of questions that do not ask about health "benefits" directly but do cover this criterion. For example, is the medical purpose of the app defined (*App Check*), or which health problem does the app want to prevent or reduce and what healthy behavior does the app want to promote (*GGD Appstore*). And there is a set of questions that do not ask about "health" benefits directly but also covers this criterion by assessing proven app usage benefit and advantages (*Tic Salut Social*).

The framework can capture if evidence about the claimed benefits is available.

If the AF asks about what benefits the app is claiming to have, it is always followed by verification of the claimed benefits evidence availability. This verification across AFs is usually done by asking if there is published, publicly, scientific, or clinical evidence available. For most AF it is obligatory that the app can provide evidence if it is claiming to have health benefits.

Some AFs do not explicitly mention "evidence", but they capture content and information sources (*MySNS Seleção*) and they ask if identified specialized professionals or a health department or a scientific society validated the content (*Tic Salut Social*).

If there is no renowned evidence available, some AFs ask for an explanation of how the app content was developed and if is it relevant and reliable (Safety and Quality Strategy in Mobile Health Apps).

In addition to capturing evidence of claimed benefits, few AFs ask for claimed benefits and supporting evidence to be made available in the product description (Pas 277:2015, BSI), or within the app (*ORCHA*).

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Level 2

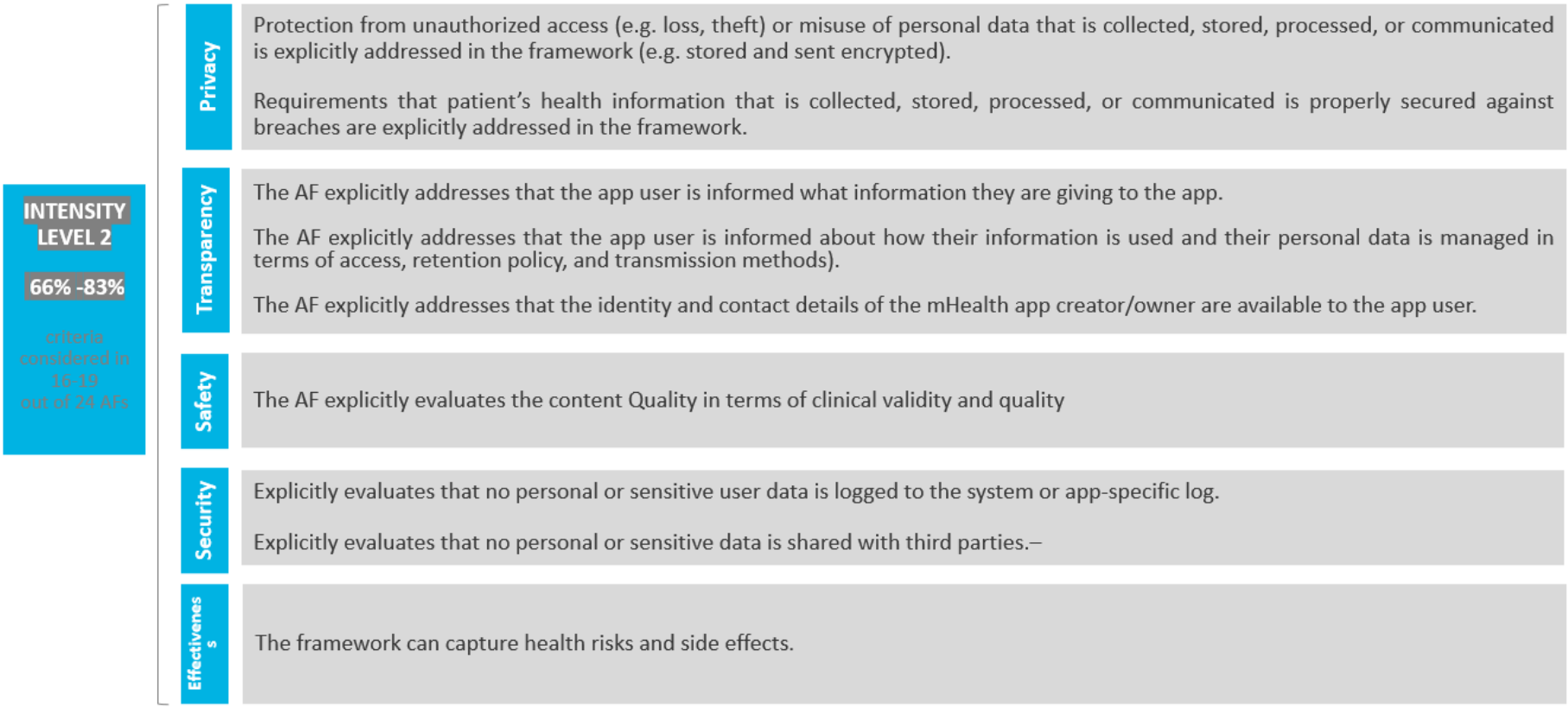

Figure 14. Criteria coverage – intensity level 2

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Level 3

INTENSITY LEVEL 3
50% -66%
criteria considered in 12-15 out of 24 KEs

Transparency	Explicitly addresses that the app user is informed who is distributing, financing, and developing the app.
Safety	Explicitly evaluates that safe communication (encrypted) of data is done. -
Security	Explicitly evaluates that cryptographic security is in place (at rest and in motion).
Reliability	Explicitly evaluates whether the app is consistent in its functions.
Validity	The framework considers whether the app utilizes scientific literature and medical expertise in the clinical validation phase of an app. Explicitly evaluates if medical data and information is backed by health professionals/Clinicians/health authorities.
Interoperability	Published data formats (e.g. standards like XML, or JSON) for import/export and transmission to different information systems (e.g. EHR) are explicitly addressed in the framework. Function of the mHealth solution on multiple platforms is explicitly addressed in the framework. Open, transparent and/or harmonised standards for data sharing are explicitly addressed in the framework.
Technical stability	Sensitive data is not exposed and security is not compromised if application crashes (due to any reason). Application can operate without a cellular network/Wi-Fi (with no risk of data compromise).
Effectiveness	The framework can capture different levels of evidence (e.g. expert opinion, observational study, randomized controlled trial (RCT), systematic review of RCT's). The framework can capture the app's applicability by distinguishing different subgroups (e.g. gender, age, health literacy).
Accesibility	The framework considers techniques to increase accessibility (e.g. Increasing text visibility, large and simple controls, description of UI elements). Where there are limitations, the app makes them transparent (i.e. the app should make clear if it is not usable for persons with low vision and take steps to mitigate problems if possible). The framework considers national, EU and international laws, web accessibility guidelines and standards for those with disabilities or limited cognitive ability (visual, hearing, impaired speech).
User experience / usability	Does the app consider the user, the system and the context of use?

Figure 15. Criteria coverage – intensity level 3

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5. Conclusions and Recommendations

5.1 Evaluation domains and criteria

domain	Conclusion	Further explanation of the conclusion *(if needed)*	Recommendations	Main target audience(s) for the recommendation					
				Developers	System integrators	Service providers	AF owners	Quality org.	Users
Privacy	1. Majority of the reviewed AFs address privacy. This can be viewed as a successful effort of law and policymakers, focused to ensure the privacy of the personal health data. On the other hand, well-defined data sharing for the patient benefit must be possible even across borders.	The GDPR enforced by the EU created a significant milestone in addressing privacy issues. However, less attention is still placed on to how the personal data are managed in terms of access, retention policy and transmission methods.	29. The assessment domain of privacy and security should be addressed clearly and separately.						
			30. Analytics applied to the patient's data should be disclosed and assessed.						
			31. Address a concise and clear definition of privacy for AFs as well as for the user.						
Transparency	2. The domain of transparency is addressed by most of the reviewed AFs. However, the degree of detail to which the user must be informed varies. What information is handed over to the app, which interests are included by stakeholders and how algorithmic app components deal with the available	The awareness for transparency is rising but often mixed with topics like privacy. More efforts have to be taken to further raise awareness and increase the demand for more transparent information about health-related applications in general.	32. A clear and concise description of collected and processed information for the user				As assessment criterion	As assessment criterion	
			33. A clear statement about the stakeholders involved in an mHealth application				As assessment criterion		
			34. Basic but concise information about data processing algorithms must be provided for all the stakeholders				As assessment criterion	As assessment criterion	As test persons

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domain	Conclusion	Further explanation of the conclusion *(if needed)*	Recommendations	Main target audience(s) for the recommendation					
				Developers	System integrators	Service providers	AF owners	Quality org.	Users
	information is often not sufficiently covered.								
Safety	3. Few details are given on the generality of frameworks about what consideration they have in terms of safety		35. Create a clear distinction on what is safety and security and create a separate topic for safety focusing on clinical safety.						
			36. Put development efforts on addressing patient clinical safety.						
			37. On connecting services with devices, there is a need for the health institutions, such as healthcare providers, to assess also the safety of the service. This might be applied for contracting developers to create these services.					Health institutions	
	4. International AFs don´t pay as much attention to safety than national/regional ones		38. Safety is an important subject that protects the user against harm of using the application and must be a redesign subject in international frameworks						
	5. User input validation is not addressed in most frameworks		39. Safety on user input is a growing concern and needs to be considered on every framework.						

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domain	Conclusion	Further explanation of the conclusion *(if needed)*	Recommendations	Main target audience(s) for the recommendation					
				Developers	System integrators	Service providers	AF owners	Quality org.	Users
			With the advancement of sport trackers, digital scale readings, and the amount of health data generated by the user, it is important to verify that some validation to it is done.						
Reliability	6. Despite a few instances refer directly to Reliability, national and regional frameworks analyse reliability in more depth, this might be due to the close relation of these organizations with the citizens.		40. A more concrete approach on defining assessment questions can be a beneficial step on the broader frameworks						
Validity	7. There is room for improvement on Validity. Validity also leads to consistency and reliability of the data presented to the user, benefiting the developers and the user itself for a quality product in accordance with the standards and the latest scientific information available.		41. Frameworks across the board might advocate for more validity. This is especially true for clinical validity and to assess that the sources of clinical information are up to date. This ensures also to build up on other domains such as safety and reliability.						
			42. Health data which serves as a basis for the mHealth solution must be checked and validated using up to date materials.						

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domain	Conclusion	Further explanation of the conclusion *(if needed)*	Recommendations	Main target audience(s) for the recommendation					
				Developers	System integrators	Service providers	AF owners	Quality org.	Users
Interoperability	8. Interoperability is of major importance whenever a mHealth application is supposed to be used in the context of a larger system-of-systems. To enable the inclusion and improve the maintenance of the needed communication interfaces a documented exchange format and documentation on the used nomenclature is paramount. In this context, the implementation of harmonized/standardised communication formats and terminology is preferred. Interoperability will also be of vital importance in supporting the creation of a European Health Data Space.	The reviewed AFs do not deal with the subject of interoperability in detail. Exceptions are frameworks that originate from SDOs like HL7 functional framework for health apps. .	43. The AF might put the topic of interoperability in the right context e.g. using/referencing the EIF-Interoperability layers, I.e. to exchange information, to be integrated with professional systems, to enable scalable solutions, interoperability is of major importance. All should be aware that for complex health services integration of the mHealth app with other systems it might be necessary.						
			44. The AF might reference to existing frameworks/organisations that provide solutions for standardised communication interfaces and terminology.						
			45. The assessment framework might demand that the health apps disclose the data model and services to facilitate an interface with the app.						
Technical stability	9. None of the existing frameworks covers the Technical stability criteria	None of the existing frameworks fully covers the Technical	46. It is important that the assessed application can maintain its level of performance and have consistent technical						

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domain	Conclusion	Further explanation of the conclusion *(if needed)*	Recommendations	Main target audience(s) for the recommendation					
				Developers	System integrators	Service providers	AF owners	Quality org.	Users
	fully (all sub-criteria included).	stability domain, including all the criteria.	functionality. Consider including Technical stability criteria into your framework.						
			47. It is important to do detailed performance testing (load test, stress test, spike test, etc.) and have evidence of it.						
			48. Regular application monitoring, tracking the number of app crashes and uptime, and updating FAQ regularly should all be standard and mandatory.						
Effectiveness	10. Effectiveness is addressed in more than 50% of the AFs, but only a few AFs fully cover the effectiveness domain (in terms of having all the criteria covered).		49. It is important to check whether the app is evaluated against any claimed health benefit or improved health outcome, and what are the potential risks and side effects of using the application.						
			50. It is important to point out and assess the risks and side effects that can be caused using the application.						
			51. It is important to measure whether the desired or intended result of the application usage						

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domain	Conclusion	Further explanation of the conclusion *(if needed)*	Recommendations	Main target audience(s) for the recommendation					
				Developers	System integrators	Service providers	AF owners	Quality org.	Users
			has been achieved (e.g. improved health outcome).						
			52. More explicit reference to key ethical concepts should be included in the design of mHealth apps.						
Accessibility	11. The understanding of the term "Accessibility" varied across frameworks. Text or image readability/size were mentioned, but beyond general design guidelines, not many recommendations or further input was found.		53. Guidelines or standards would be of value to ensure accessibility in health app-related context of use, to bridge a common understanding of the design for such apps. In health environments, it is especially important to adequately include all potential target users.						
Scalability	12. Although very important, scalability is only seen in terms of connection to other services and devices. Not much attention is giving to a process of expansion of services to other geographies and cultures.		54. Frameworks need to account also for the expansion process of an mHealth solution, either from a start up to a wider application, or from a mature regional application to an international setting.						
User experience/Usability	13. User experience and/or usability was addressed by approximately half of the AFs, a few in a detailed way		55. Frameworks need to provide the criteria, justification and guidelines publicly available. These elements would provide						

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domain	Conclusion	Further explanation of the conclusion *(if needed)*	Recommendations	Main target audience(s) for the recommendation					
				Developers	System integrators	Service providers	AF owners	Quality org.	Users
	with public usability criteria and metrics, others at a general level. Several AFs mention ISO-standards and certification.		developers, users and authorities with useful information to apply and assess health apps.						
Security	14. There are few frameworks that evaluate the security in terms of technical aspects.		56. Incorporating some depth in the analysis of security is a need and subjects such as network security and communication protocols should be evaluated to include it in the assessment process in frameworks. This allows to build up also on privacy and reliability domains.						

Table 11. Conclusions and recommendations regarding evaluation domains and criteria

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5.2 Health apps repositories

In a similar way to what happens in the AFs, **there is much heterogeneity among the apps repositories when it comes to their features**, for example size of the repository, connection or not with a clear and transparent assessment process and/or quality seal, and specially the deployment of a rich interface with different filters that might help the user to get valuable information from the repository.

In this sense, the recommendation to AFs owners would be to work more intensely on developing repositories with helpful tools for the reader, that might become a facilitator for increasing the mHealth adoption by patients, relatives or health professionals.

5.3 Qualitative insights about the assessment frameworks

One of the main objectives of this report is to **learn from the experience** of the existing AFs and their approach to implementing certain aspects, such as assessment processes, business and sustainability models, guidance and communication with target audiences, etc. In this sense, public or private entities planning implementations of their own assessment frameworks could benefit greatly from the experienced captured by the AFs reviewed in the report. They should avoid reinventing the wheel, and benefit from the lessons learned and experienced of the existing AFs which can be scaled up across Europe.

Both governmental and non-governmental organisations are involved in the **creation and maintenance** of AFs, which are carried out at national and/or regional levels. While most owners aim to update their frameworks according to the most current regulatory and legislative aspects, this varies greatly between AFs (between one and three years) and only few of them managed to achieve this aim until now. Maintaining AFs continuously is key to ensuring they are fit for purpose, reflect the quickly moving legislative and non-legislative landscape in Europe, and address current needs of the various audiences addressed, especially those of health app developers, which are often SMEs.

Several AFs receive world-wide applications and have content available in English, but some are limited by the **language of the app** and assess only apps in their national language (the app repository also containing information in the national language or the local dialect). While most frameworks operate on a **voluntary** basis, where the use of the framework provides secondary benefits, only a few frameworks are of **mandatory** nature, therefore not contributing to integration within the healthcare system. Incentives should be in place to ensure that the apps developed are interoperable and can be integrated into existing health systems and services.

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The frameworks mainly aim to **increase confidence** in citizens and health professionals regarding the use and adoption of health apps. The assessment process provides several benefits to app developers, such as the inclusion in a repository, a detailed results report which can be used to improve the app, or a quality seal/recognizable vignette that increases the trust. However, these benefits are not present in all the AF and they vary to a great extent. Clear **communication about the benefits** is therefore key to the AF's wider adoption. The benefits are more attractive with an increase of the AF's repository and achieving critical mass. In this regard, cooperation across AFs (e.g., mutual recognition systems) could benefit greatly their uptake and attractiveness for health app developers, reinforcing a positive development circle.

Several frameworks have a clearly defined **process** and steps that an app developer must follow to submit their app. The complexity of the process varies greatly between frameworks and sometimes within the same framework for different types of apps. The majority of frameworks have published information on their website regarding the process and the involved questions. Most of them yield either a quantitative outcome represented by a general score, or a qualitative outcome, represented by a quality seal or a recognisable vignette. While some frameworks require both self-assessment and owner assessment, some are performed by the AFs owners or designated experts. Few frameworks are intended as guidelines and can serve for app developers as self-assessment or can be used for as a third-party guideline for commissioners and other interested stakeholders. The assessment process varies to great extent (between a week and up to three-six months). While few frameworks are transparent about the time, some do not mention at all the required period. It is therefore important to app developers to have a clear understanding of the expectations, the evaluation process, the roles and timing leading to an assessment outcome and inclusion of the app into the framework. If costs are involved, they should be made transparent from the start.

5.4 Patient organisations and quality of apps

The work carried out for this report on patient organisations trends and experiences showed that **patient organisations have health apps on their agenda** and are interested in how self-management and the everyday life of their members can be supported.

However, challenges regarding **safety and reliability** were addressed particularly related to **data storage and privacy**. Other challenges mentioned were the **lack of transparency**: "*Who funded and created the health app*?"; **accreditation, reliability and validity**: "*Who advised the medical content?*". Several patient organisations have user panels and technical expert's groups to address those issues, but others have not or work on a policy or framework's level.

Challenges currently faced by patient organisations include **the conventional organisation of health services that does not specifically include mHealth as a core element,** and how to make health apps become a structural part of it. The "objective verification of reliability and validity made by a governmental institution, patient organisation or third trusted party" is seen

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by some patient organisations as an unmet need for health services to use and recommend apps to patients.

Another challenge refers to the **pace of technological development and the overwhelming amount of new and available apps** on different platforms. Instead of recommending specific apps, some of the patient organisations choose to present apps in a generic way and highlight important factors to consider when selecting apps for personal use, therefore leaving to the individual the last word on their choice.

User-involvement and co-design were mentioned as relevant methods for creating apps that meet personal needs and involve users in the process. However, one patient organisation argued that it is not enough to engage one single patient once in the development- there needs to be continuous user involvement throughout the entire development cycle, including up-dates and refinements. Another key learning for future was exposed in this way: "*Which problems can be solved by mHealth solutions*?".

Note: for results under headings 4.7, 4.8, 4.9, 4.10 and 4.11, the text developed there gathers enough key considerations that would make redundant to reformulate it as conclusions or recommendations.

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Annexes

Annex 1a. List of analysed assessment frameworks

Assessment Framework	Organization	Location
Initiated, led or supported by governmental institutions		
Safety and Quality Strategy in Mobile Health Apps	Andalusian Agency for Healthcare Quality (ACSA)	Andalusia (Spain)
Accreditation Service and TICSS guarantee certification	TIC Salut Social Foundation	Catalonia (Spain)
Digital Assessment Questions (DAQ)*	NHS Digital	United Kingdom
mHealthBelgium	Belgian Federal Government (Multistakeholder initiative; platform operated by *Agoria* and *beMedTech*, in cooperation with *FAMHP, NIHDI, eHealth Platform*)	Belgium
MySNS Selecçao	*SPMS* - Shared Services of the Ministry of Health, EPE	Portugal
Evidence Standards Framework for Digital Health Technologies	National Institute for Health and Care Excellence (NICE)	United Kingdom
Good practice guidelines on health apps and smart devices	High Health Authority (HAS)	France
App Check (DiaDigital and PneumoDigital)	Center for Telematics and Telemedicine (ZTG GmBH)	Germany
Criteria catalogue for self-declaration of the quality of health apps	eHealth Suisse - Swiss Competence and Coordination Centre of the Confederation and the Cantons	Switzerland
MindApps.dk: apps for mental health **	Centre for Telepsychiatry, Region of Southern Denmark	Region of Southern Denmark (Denmark)
PAS 277:2015 Health and wellness apps – Quality criteria across the life cycle – Code of practice	Published by the British Standards Institution (BSI) and sponsored by Innovate UK	United Kingdom
AppKRI (meta-catalogue of criteria)	Fraunhofer Institute for Open Communications (Project funded by the Federal Ministry of Health)	Germany
AppQ	Bertelsmann Stiftung (funded by the Federal Ministry of Health)	Germany
BfArM DiGA-Fast-Track and Guidance Document	Federal Institute for Drugs and Medical Devices (BfArM)	Germany
GGD AppStore	Association of Regional Public Health Services (GGD) and Regional Medical	Netherlands

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	Emergency Preparedness and Planning (GHOR)	
Non governmental initiatives		
ORCHA Review process	Organisation for Review of Care and Health Apps ORCHA	United Kingdom
My Health Apps	PatientView	United Kingdom
ISO/TS 82304-2 Health and wellness apps - Quality and reliability	CEN/TC 251 and ISO/TC 215	Worldwide
iSYS score	iSYS Foundation	Catalonia (Spain)
DEKRA Certification - MEDAPPCARE	Meddappcare (Dekra Group)	France
Our Mobile Health ***	Our Mobile Health	United Kingdom
cMHAFF: Consumer Mobile Health Application Functional Framework	Health Level Seven International (HL7)	Worldwide
Continua Design Guidelines (CDG)	Personal Connected Health Alliance (PCHA)	Worldwide
Report of the Working Group on mHealth Assessment Guidelines	European Commission	European

Table 12. Assessment frameworks developed in Europe

* The way apps and digital tools are assessed for use by the NHS has changed. Now the framework is named "Digital Technology Assessment Criteria for health and social care (DTAC)", the new national baseline criteria for digital health technologies entering into the NHS and social care, created in 2021. https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/

** Website currently under maintenance. They have decided to give mindapps.dk a short break so they can relaunch it in a new format around October 2021.

*** Website is not active

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Annex 1b. AFs owners' feedback to case files and participation in the webinar

Assessment Framework	Feedback to case file received	Participation in the webinar (June 2020)
Initiated, led or supported by governmental institutions		
Safety and Quality Strategy in Mobile Health Apps	Yes	Yes
Accreditation Service and TICSS guarantee certification	Yes	Yes
Digital Assessment Questions (DAQ)	No	No
mHealthBelgium	Yes	No
MySNS Selecçao	Yes	Yes
Evidence Standards Framework for Digital Health Technologies	Yes[82]	No
Good practice guidelines on health apps and smart devices	No	No
App Check (DiaDigital and PneumoDigital)	Yes	Yes
Criteria catalogue for self-declaration of the quality of health apps	Yes	No
MindApps.dk: apps for mental health	Yes	No
PAS 277:2015 Health and wellness apps – Quality criteria across the life cycle – Code of practice	Yes	No
AppKRI (meta-catalogue of criteria)	No	No
AppQ	Yes	No
BfArM DiGA-Fast-Track and Guidance Document	Yes	No
GGD AppStore	No	No
Non governmental initiatives		
ORCHA Review process	Yes	Yes

[82] This feedback arrived 15th July, so it has not been feasible to include the updated information in the Qualitative Insights section of this D2.1 Draft Report V 0.2. It will be uploaded for the final version.

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My Health Apps	Yes (partially)	No
ISO/TS 82304-2 Health and wellness apps - Quality and reliability	Yes	Yes
iSYS score	Yes	No
Medappcare Quality Approach	No	No
Our Mobile Health	No	No
cMHAFF: Consumer Mobile Health Application Functional Framework	Yes	Yes
Continua Design Guidelines (CDG)	Yes	Yes
Report of the Working Group on mHealth Assessment Guidelines	N/A	N/A

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Annex 2a. Interview guide for patient organisations

1. Has your organisation identified any needs for digitalisation among the patients it represents? If yes, could you enumerate and describe briefly the 3 most important/ demanded/urgent.

2. Is the quality and reliability of health apps a matter of interest for your organisation? To what extent?

3. Have you carried out/or collaborated with any initiatives on mHealth apps in general? Do you see any approach/trend/model going on in your region/country/Europe?

4. In which direction is your organisation working?
    a. Do you follow/recommend any existing application frameworks?
    b. Do you receive/have a dialogue on mHealth apps with your users/patients' group?

5. To what extent does your organisation consider that mHealth apps can meet the needs described in question 1? Do you have any key lessons learnt about quality of mHealth apps?

Annex 2b. Patients' organisations consulted

Organisation	Type of interaction	Date
European Patients' Forum	Digital interview	June 2020
The Danish Lung Association	Digital interview	June 2020
The Norwegian Diabetes Association	Digital interview	May 2020
The Danish Multiple Sclerosis Society	Digital interview	June 2020
PatientView	Email-communication	June 2020
International Diabetes Federation (IDF), Europe	Desk research (position paper)	June 2020

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Annex 3. Assessment frameworks case files

Framework Name	Safety & Quality Strategy in Mobile Health Apps
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	The Safety and Quality Strategy in Mobile Health Apps is a dynamic and integrated process which offers suggestions and advice for general citizenship and a list of recommendations is recognised with the granting of the *AppSaludable* Quality Seal. The Seal was created by the Andalusian Agency in Spain and it`s used to recognise reliable mobile applications. The process includes both the self-assessment of the app in accordance with recommendations included in the guide, and the assessment carried out by a committee of Agency's experts to identify possible improvements. Once the seal is awarded, the app becomes part of a list of mobile health apps with remarkable safety and quality. The process is free and open to all public and private apps, both Spanish and from other countries.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	The Andalusian Agency for Healthcare Quality https://www.sspa.juntadeandalucia.es/agenciadecalidadsanitaria/en/ Spain
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	The Andalusian Agency for Healthcare Quality
Owner Type	Governmental institution / state-run agency
Year of Creation	2012
Website / Web Presence	http://www.calidadappsalud.com/en/

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Update Frequency *Is the framework revised and updated periodically? How often?*	The process is reviewed annually, taking into account all regulatory and legislative aspects in force in the market at that time. While the recommendations are general, the specific requirements of each recommendation are articulated to ensure that the assessment considers these updates and does not have an excessive impact on the wording of the broader general recommendations.
Last Update	Currently, the model is being updated according to the joint work being done in the Twinning *AppSaludable*, in a collaborative environment with Portugal and Belgium. It is estimated that this update will be completed before the end of 2020.
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	International: both Spain and other countries Only limitation is language of the App. Mainly focused on Spanish language apps. Nevertheless, some assessments have been carried out with English language apps.
Conformity Basis	Voluntary – the use of the framework provides some secondary benefits, such as exposure, addition to a curated library, etc.
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Citizens Developers Health professionals Health Service Suppliers The *AppSaludable* Quality seal awarded after the framework assessment is a guarantee seal which is used to recognize reliable mobile apps. After the seal is awarded, the app is included in a list of mobile health apps with remarkable safety and quality. The AF recognizes through the awarded seal the reliability of the assessed app, which is important both for citizens when using them and for developers, which can certificate the usability of the app.
Assessment Subject	Health apps in general, increasing their exposure.
Assessment Domain Coverage *Which assessment domains does the framework*	

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
Privacy	x		

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address specifically? Does the framework consider, somewhat considers or does not consider the domains?				
	Transparency	x		
	Safety		x	
	Reliability			x
	Validity		x	
	Interoperability		x	
	Technical stability			x
	Effectiveness/Efficacy/Efficiency		x	
	Accessibility	x		
	Scalability		x	
	User experience and usability	x		
	Security		x	

Is there a clear process detailing how the assessment framework is to be applied? Please describe.

The seal is based on the 31 recommendations published in the Guide of recommendations on Design, Use and Assessment of Health Apps. The recommendations are structured in 4 sections:

- Design and Appropriateness
- Quality and Safety of Information
- Provision of Services
- Confidentiality and Privacy

The process includes both the self-assessment of the app in accordance with recommendations included in the guide, and the assessment carried out by a committee of Agency's experts (evaluation team) to identify possible improvements.

The Distinctive is based on a Pass/fail schema. Some of the recommendations are mandatory and some other are voluntary.

The outcome of the assessment framework is qualitative, represented by the award of the *AppSaludable* Quality Seal, which guarantees the reliability of the mHealth app.

Roles:

The model has a committee of experts to identify possible improvements to be incorporated.

External evaluators, specialized in different areas of evaluation, which are used according to the type of app to be evaluated.

Mentors that synchronize the activity of these evaluators and are in charge of mentoring those responsible for apps that go through the process and need it.

The process follows a qualitative model according to the degree of compliance with the 31 recommendations, where in each recommendation there are requirements that are mandatory and must

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	be met to obtain the Distinctive and other criteria that are not mandatory but are recommended to be met and that provide a plus of quality to the apps that go through the process. To obtain the Distinctive you must comply with 100% of the mandatory requirements and at least 60% of the non-mandatory ones.
Explain the framework's sustainability and business model.	The AF was created and is maintained by The Andalusian Agency for Healthcare Quality (ACSA). *ACSA* has economic resources from the Regional Ministry of Health which are transferred to the Fundación Progreso y Salud with the aim of financing the activity in terms of support and management for the centres and programmes managed by the Foundation. With the aim of fostering excellence in all the services related to health care and welfare, *ACSA* is involved in several projects, which receive financing via management orders, agreements and/or other specific grants. Furthermore, *ACSA* receives financing from the resources generated by its own activity through the billing of its services to its users.
Presentation and visualization of the assessment results	Full assessment reports are generated and shared with the app development team. The catalogue of apps that currently have the Distinctive and those that are in the process of obtaining it: http://www.calidadappsalud.com/distintivo/catalogo For those apps being acknowledged with the Distinctive, a summary report with major performed improvements and some outlined features are displayed in the detail page of the app catalogue.

Framework Name	Accreditation Service and TICSS guarantee certification / Servicio de Acreditación y Sello TICSS / Servei d'Acreditació i Segell TICSS
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets,*	The framework was developed for the assessment of mobile apps and devices in health and social welfare environment by the TIC Salut Social Foundation, part of the Catalan Regional Ministry of Health in Spain. The framework is based on four key criteria, which outline the essential requirements for quality and reliability of an app. Once the app has been validated, it will be published on the TIC Salut Social website in the Catalogue of Accredited apps, with the accreditation stamp. The corresponding accreditation certificate will also be delivered together with the detailed results report of the accreditation made.

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link to policy), etc.	
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	TIC Salut Social Foundation /Fundación TIC Salut Social / Fundació TIC Salut Social https://ticsalutsocial.cat/en Catalonia, Spain
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	TIC Salut Social Foundation /Fundación TIC Salut Social / Fundació TIC Salut Social
Owner Type	Governmental institution / state-run agency
Year of Creation	2015
Website / Web Presence	https://ticsalutsocial.cat/en/serveis/mhealth-en/accreditation-service-and-ticss-guarantee-certification/
Update Frequency *Is the framework revised and updated periodically? How often?*	The assessment process and criterion are revised every two years.
Last Update	The last updated was on 2018, and currently we are carrying out the revision of all the process.
Geographical Application Scope *Provide a type and name the actual*	International: both Spain and other countries

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geographical location(s).	
Conformity Basis	The process is mandatory if the app has to be integrated in the system. Otherwise, it remains voluntary.
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Policy makers Developers Health professionals Researchers Others: Citizens For developers, the app will be published on the TIC Salut Social website in the Catalogue of Accredited apps, with the accreditation stamp. They will also receive an accreditation certificate together with a results report. The Catalogue increases the app exposure while offering freely accessible quality information for all interested citizens.
Assessment Subject	Mobile applications and devices in the health and social welfare environment / health and wellness apps
Assessment Domain Coverage *Which assessment domains does the framework address specifically?* *Does the framework consider, somewhat considers or does not consider the domains?*	

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
Privacy		x	
Transparency	x		
Safety		x	
Reliability		x	
Validity			x
Interoperability			x
Technical stability		x	
Effectiveness/Efficacy/Efficiency		x	
Accessibility	x		
Scalability			x
User experience and usability		x	
Security		x	

Is there a clear process detailing how the	The accreditation process has been differentiated into three phases: • Phase 0: Review of the application. • Phase 1: Initial Technical validation and functional accreditation.

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assessment framework is to be applied? Please describe.	• Phase 2: Technical accreditation. In Phase 1, an initial technical validation process is provided by testing the application. The functional accreditation of the application is provided by the Functional Experts Committee of the mHealth Office (entities such as *COMB, COPLEFC, COIB, SCEPC, AiFICC* and *CAMFiC*) by reviewing the App and evaluating the content criteria. Phase 2 contains Technical accreditation, where the usability block, the technology block and the security block are reviewed. The AF has four blocks: Usability and accessibility, Technology, Security, and Functionality and content. During the accreditation process, apps will be assessed according to all four blocks. At the end of the accreditation process, the mHealth Office will grant a numerical mark resulting from the evaluation criteria of those Apps which have successfully overtaken the minimum compulsory requirements. Each one of the Apps that pass that process will have a numerical score related to the result of having OVERCOME the accreditation process. This score will be calculated by the sum of partial marks of each evaluated block; each block will have a weight equivalent to the 25% of the total score. A formula of the score is provided in the Accreditation Criteria guide. The minimum requirements or compulsory compliance for getting the accreditation is to overcome the conditions where the label is COMPULSORY. Otherwise, the App could not get the certificate of accreditation and it will be excluded. This procedure will be repeated in each block and will only be effective if all necessary requirements are overtaken. Physicians, nurses, psychologist, experts in physical education and sports, technical developers, usability experts and data protection experts are doing the assessment of the process. The mHealth Office in TIC Salut Social Foundation is coordinating the process with the different experts. TIC Salut Social is a public agency within the Catalan Regional Ministry of Health, so the entity who develop the process is a public entity in Catalonia. The processes are: - Revision of the accreditation's request - Initial validation and classification on levels of risk - Functional accreditation (corresponding in the revision of the first block) - Technical accreditation (corresponding in the assessment of the other three blocks (usability, technical and security aspects) - Final report and Certification Stamp

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How long does a typical assessment take?	The completed assessment takes more or less 8 weeks, from the requested that is delivered in the mHealth Office to the final report with the results. The period could be extended in the case of having some technical problems in the use of the app or if there are some discussions into the Committee of experts about some criteria that the experts don't have a clear consensus. In that case, the discussions within the group may lead to lengthen the response time.
Explain the framework's sustainability and business model.	Accreditation rates are perceived for the assessment. The accreditation process, blocks, rates, and payment model are described in a guide published on the TIC Salut Social website. Fees Phase 0 Review of the application - free Phase 1 Initial technical validation and Functional accreditation- 999,00 € Phase 2 -Technical accreditation - 2.000 € Other considerations and additional charges: If reviewed separately, Basic Security Module: 975 € Basic Technological Module: 975 € Basic Usability Module: 975 € Surcharge applicable to applications that exceed the standard volumetry. The additional screen surcharge will be applied: 60 € Surcharge for each external device with which the app interacts. The device is not certified: 170 € Revalidated. Whether you do not pass any of the accreditation blocks, you can review the process again, paying 50% of the cost: 50% Accreditation review (The duration of the accreditation will be annual. The mHealth Office will decide if the accreditation should be carried out again or if it is not necessary. The developers are committed to notify the *mHealthOffice* of the new versions and changes that involved): 100% Security audit (Depending on the criticality of the application, the mHealth Office may request a security audit): evaluated in each case Payment model Once the application has been reviewed (Phase 0), a quote will be delivered with the cost of the accreditation process for the specific App.

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	At the moment of receiving the quote signed, the invoice corresponding to the accreditation process will be issued At the moment that the applicant receives the notification will have a maximum period of 10 working days to make the payment by credit card or bank transfer in the account number indicated on the invoice issued. This payment will start Phase 1 and Phase 2 in parallel, where the initial validation, functional accreditation and technological accreditation of the App will be carried out. In the case of not making the payment during the indicated period, the applicant will be notified by email indicating that the request is cancelled if the payment is not made within 5 business days. Once Phase 1 and Phase 2 have been evaluated, the mHealth Office will send an email to the applicant with the result of the accreditation. In the event that a developer has pending the payment of one or more Apps, under the discretion of the head of the mHealth Office initiate any registration procedure of App. In the case of not satisfactorily overcoming the accreditation process, the corresponding "results report" will be delivered where the points not exceeded are detailed and pertinent comments will be made. If in a maximum of six months the changes are presented, the application will be revised again, bearing in mind that if the App fails in more than three criteria of a block, 50% of the price of that block must be paid.
Presentation and visualization of the assessment results	Repository showing the apps that have passed the accreditation process: https://ticsalutsocial.cat/es/apps/ This repository is available in three languages: Catalan, Spanish and English. ACREDITADA · FUNDACIÓ TIC SALUT SOCIAL ·

Framework Name	Digital Assessment Questions (DAQ)
Short Description *What is the purpose of the*	Digital assessment Questions is an assessment framework developed by NHS Digital which aims to help users find trusted health and wellbeing apps that have been assessed to be clinically safe and secure.

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framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.	The apps are assessed against a range of NHS Standards. Once approved, the apps are published on the NHS Apps Library.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	NHS Digital https://digital.nhs.uk/ UK
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	NHS Digital
Owner Type	Governmental institution / state-run agency
Year of Creation	2017
Website / Web Presence	https://digital.nhs.uk/services/nhs-apps-library
Update Frequency *Is the framework revised and updated periodically? How often?*	No available information
Last Update	17/05/19

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<table>
<tr><td>Geographical Application Scope
Provide a type and name the actual geographical location(s).</td><td>International: both UK and other countries</td></tr>
<tr><td>Conformity Basis</td><td>Voluntary – the use of the framework provides some secondary benefits, such as exposure, addition to a curated library, etc.</td></tr>
<tr><td>Target Audience(s) and Value Propositions
List the main target audiences and elaborate the value the framework offers to them.</td><td>Policy makers
Developers
Health professionals
Researchers
Others: Citizens, Commissioners

Assessed and approved products will be published on the NHS Apps Library, offering developers increased exposure and reassuring users and commissioners.
Benefits are listed, such as:
the product will reach the wider NHS community, helping to increase uptake and making it more appealing to commissioners
it’s the only place to find every health app and digital tool that has been assessed to NHS standards
the number of visits to the library is growing and currently stands at around 25,000 visits a week
visits to the NHS Apps Library have a 15% click-through rate to the App Store and Google Play
the NHS Apps Library is signposted from relevant health and wellbeing pages across the NHS website, which receives more than 30 million visitors a month
apps published on the library are available through an NHS API</td></tr>
<tr><td>Assessment Subject</td><td>Health apps in general, medical apps etc.</td></tr>
<tr><td>Assessment Domain Coverage
Which assessment domains does the framework address specifically?</td><td>
<table>
<tr><th>Domain</th><th>Considers
>65% criteria “yes”</th><th>Somewhat considers
The rest</th><th>Does not consider
None criteria “yes” or “somewhat”</th></tr>
<tr><td>Privacy</td><td>x</td><td></td><td></td></tr>
<tr><td>Transparency</td><td>x</td><td></td><td></td></tr>
</table>
</td></tr>
</table>

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Does the framework consider, somewhat considers or does not consider the domains?	Safety		x	
	Reliability		x	
	Validity	x		
	Interoperability	x		
	Technical stability		x	
	Effectiveness/Efficacy/Efficiency	x		
	Accessibility	x		
	Scalability			x
	User experience and usability	x		
	Security		x	
Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The questions have been designed by experts from technical and policy backgrounds, and cover national standards, regulations, and industry best practice. The number of questions depends on a product`s complexity, potential clinical effectiveness, and data protection responsibilities. The technical assessment and standards include questions related to: • Available evidence on outcomes • Clinical safety • Data protection • Security • Usability and accessibility • Interoperability • Technical stability.			
How is the assessment performed?	• Self-assessment • Assessment by NHS experts and NHS approved assessors Developers are required to answer a series of questions, which will be further reviewed by NHS experts or NHS approved assessors.			
Explain the framework's sustainability and business model.	No available information			
Presentation and visualization of the assessment results	NHS app library https://www.nhs.uk/apps-library/			

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Framework Name	mHealthBelgium
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	*mHealthBelgium* is the Belgian platform for mobile apps that are CE-marked as a medical device. This unique platform centralises all relevant and required information on mobile apps for patients, healthcare professionals and healthcare institutions in three languages (Dutch, French and English). The information is related to CE marking, data protection, communication security, interoperability with other IT systems and the way in which the app is financed. *mHealthBelgium* consists of a validation pyramid with three levels. An app always enters at the lower level, M1, and can climb in hierarchy via M2 to the top level, M3.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*mHealthBelgium* is a joint initiative of the Belgian Federal Government and the Belgian (medical) technology industry, supported by the Ministry of Public Health. As a consequence, it is a multistakeholder initiative. The criteria for each of the 3 levels of the validation pyramid are defined by the 3 corresponding national authorities: The FAMHP (Federal Agency for Medicines and Health Products) is the competent authority for all things related to the quality, safety and efficacy of medicines and health products, including medical devices. Is responsible for level M1 within *mHealthBelgium*. The eHealth Platform is a federal government institution with the mission to promote and support the providing of a well-organised, mutual electronic service and exchange of data between all healthcare stakeholders with safeguards in the areas of data security, the privacy of the patient and the caregiver, respecting medical professional confidentiality. Is responsible for level M2 within mHealthBelgium. The NIHDI (National Institute for Health and Disability Insurance) is responsible for the refunding of medicines, medical devices and medical provisions. Is responsible for level M3 within mHealthBelgium.
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	The *mHealthBelgium* platform is managed by beMedTech (sector federation of industry of medical technologies) and Agoria (sector federation of technological industry). Beyond the platform, the framework itself is a joint initiative between the Belgian Federal Government and the technology industry.

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Owner Type	Platform management: non-for-profit non-governmental institution Framework ownership: Joint initiative (gov institution + industry)
Year of Creation	2018, but platform only implemented and active since January 25 2019
Website / Web Presence	https://mhealthbelgium.be
Update Frequency *Is the framework revised and updated periodically? How often?*	Periodically: continuous updates if needed, but at least 1x per year the content is fully checked The aim is every year, but this has not been followed rigorously
Last Update	June 2020
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	National: Belgium
Conformity Basis	Mandatory – part of local/regional/national/international legislation Remark: it is optional to ask the *mHealthBelgium* quality label and be visible on the portal, so not mandatory to be commercially active in Belgium, but mandatory if you want to strive for financing / reimbursement by the national authority
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Developers Health professionals patients (broad public: every citizen) *Value proposition:* For companies: quality label for their product For citizens: list of reliable apps with many detailed and structured info per app via app leaflet
Assessment Subject	Only medical apps are allowed, so apps that are medical devices and consequently CE certified (no matter the class type)

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Assessment Domain Coverage *Which assessment domains does the framework address specifically? Does the framework consider, somewhat considers or does not consider the domains?*	Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
	Privacy		x	
	Transparency		x	
	Safety			x
	Reliability			x
	Validity			x
	Interoperability		x	
	Technical stability			x
	Effectiveness/Efficacy/Efficiency		x	
	Accessibility		x	
	Scalability			x
	User experience and usability		x	
	Security		x	
Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The app assessment framework is a validation pyramid with 3 levels. An app always enters at the lower level, M1, and can climb in hierarchy via M2 to the top level, M3. To be allowed to the next level, you first need to fulfil all criteria of that level. More info on https://mhealthbelgium.be/validation-pyramid Every level has its own automated process with predefined flows.			
How is the assessment performed?	The AF includes a quality seal. The criteria are made by the national authorities and are checked by the coordinators of the platform. Where possible, automatic test centres have been built to verify the criteria. Otherwise, human assessment will be done, by relying on experts within the authorities to control the statements and finally judge.			
How long does a typical assessment take?	Assessment to level M1 in general takes max a few days but can also be done the day itself if all fields are filled in correctly from the beginning.			
Explain the framework's	Companies who want to get the *mHealthBelgium* quality label and hence be visible on the portal, pay a yearly fee of 1000 euros (25% reduction for those who are member of *Agoria* and/or *beMedTech*). This			

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sustainability and business model.	budget will be used to maintain the platform and is an incentive (at least yearly) for the providers to keep the app info up to date.
Presentation and visualization of the assessment results	Overview of all granted apps in 1 library with different filters (e.g., pathology, function, users, language, pyramid level) to search easily. https://mhealthbelgium.be/apps

Framework Name	MySNS Selecção
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	*MySNS Selecção* is an app store which is part of the *MySNS* community. The objective of the framework is to facilitate the opportunity to share mobile applications developed by health institutions, companies, individuals who, according to European guidelines, have a significant role in bringing health closer to the citizen.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*SPMS* - Shared Services of the Ministry of Health, EPE (Portugal) is the entity responsible for the *MYSNS Selecção* creation and management. *SPMS* has the nature of a legal person of public law of a business nature, endowed with legal personality, administrative and financial autonomy and its own assets, under the legal regime of the State's business sector, approved by Decree-Law no. 133/2013, of October 3, being subject to the supervision of members of the Government responsible for the areas of finance and health. Entity website: http://www.spms.min-saude.pt/
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	SPMS, EPE.

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Owner Type	Governmental institution / state-run agency
Year of Creation	2018
Website / Web Presence	https://www.mysns.min-saude.pt/mysns-selecao/
Update Frequency *Is the framework revised and updated periodically? How often?*	The aim is to revise the framework periodically, however the timeframe was not defined yet.
Last Update	2018
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	National: Portugal
Conformity Basis	Voluntary – the use of the framework provides some secondary benefits, such as, improve the quality of healthcare apps.
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	• Citizens; • Health professionals; • Developers and software companies that develop health apps. This framework aims to promote confidence to citizens and health professionals regarding the use and adoption of health application. Additionally, programmers/ software companies will also benefit from the guidance provided by the framework criteria and good practices, offering a competitive advantage for the development of digital services.
Assessment Subject	Health apps in general
Assessment Domain Coverage *Which assessment domains does the framework*	

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"

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address specifically? Does the framework consider, somewhat considers or does not consider the domains?	Privacy	x		
	Transparency	x		
	Safety		x	
	Reliability		x	
	Validity		x	
	Interoperability			x
	Technical stability		x	
	Effectiveness/Efficacy/Efficiency		x	
	Accessibility		x	
	Scalability			x
	User experience and usability			x
	Security	x		

Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The first step is done by health app owners and includes the revision of all the framework requirements in order to apply for the quality seal. The second step is to fill the form application in the website in order to submit the app to the evaluation process. In phase 3, the applications are evaluated by a group of experts in terms of performance, security and public utility using qualitative scores. If the apps comply with all the evaluation criteria, they obtain the quality seal "Selected" and will be part of the *MySNS Selecção* library available in the website. The apps that need to perform improvements in some criteria, they will acquire the "Pre-Selected" seal.
How is the assessment performed?	The apps are evaluated by external experts and the ones that comply the defined requirements will obtain a "Selected" or "Pre-selected" quality seal.
How long does a typical assessment take?	A typical assessment can take in average three months.
What are the benefits of applying the framework? Please relate them to the main target	The model guides programmers/ software companies to improve the quality and the portfolio of the services offered to citizens and health professionals. Moreover, it allows to raise the value and distinction of the applications bringing greater transparency to the mobile health apps market.

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audience(s) identified earlier.	In addition, it promotes the enhancement of citizen literacy and encourages the use of digital services by all the player in the health environment.
Explain the framework's sustainability and business model.	The current model is financed by the Health System Central Administration and its aim is to improve the quality of the health apps available for citizens and health professionals. In the future, the framework will be restructured and will evolve to a self-sustainable model considering an evaluation fee payed by the app´s owners.
Presentation and visualization of the assessment results	The apps that comply all the defined criteria will be presented in the app library available in MySNS Selecção website.

Framework Name	Evidence Standards Framework for Digital Health Technologies
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	The purpose of the framework is to develop standards that ensure new technologies are clinically effective and offer economic value. The standards provide: • advice to digital health innovators: • about how the NHS makes decisions • about the standards of evidence, they will be expected to produce for different types of digital technologies. Help NHS commissioners: • to make more informed and consistent decisions by providing a framework for the levels of evidence they should expect to see presented to them. • Improve the approach to developing and commissioning digital health technologies: • by making it more dynamic and value driven, with a focus on offering real value to patients.

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	The framework supports the relevant principles of the Department of Health and Social Care code of conduct for data-driven health and care technology[83].
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	National Institute for Health and Care Excellence (NICE), https://www.nice.org.uk/ United Kingdom (UK)
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	National Institute for Health and Care Excellence (NICE)
Owner Type	Governmental institution /state-run agency Non-departmental public body of the Department of Health in England
Year of Creation	2013
Website / Web Presence	https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies
Update Frequency *Is the framework revised and updated*	A further update will be issued Summer 2020.

[83] https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology

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periodically? How often?	
Last Update	March 2019
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	National: UK
Conformity Basis	Voluntary – the use of the framework provides advice on the levels of evidence to provide decisionmakers to demonstrate new technologies are clinically effective and offer economic value and promote better integration between health, public health and social care services.
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Policy makers Innovators and developers Health professionals Researchers Others: Stakeholders, NHS, Public Health and Social Care professionals Value proposition: • to reduce the risk for companies introducing products to the UK market by helping them focus on the most compelling data and • to work with companies and the NHS to design and manage novel evidence generation processes and new data-driven funding models for fast-track approval and reimbursement which provide benefits to patients and make the best use of NHS resources. • to extend our support for companies by increasing the visibility and accessibility • to support the UK in developing a world-leading approach to using data to track outcomes and manage early access to worthwhile new technologies A standardized approach to agreeing levels of evidence for technologies with different functions sends a consistent message to Innovators and health professionals and NICE is regarded as a competent authority
Assessment Subject	Health services

Assessment Domain Coverage	Domain	Considers >65% criteria "yes"	Somewhat considers	Does not

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Which assessment domains does the framework address specifically? Does the framework consider, somewhat considers or does not consider the domains?			The rest	consider None criteria "yes" or "somewhat"
	Privacy	x		
	Transparency	x		
	Safety		x	
	Reliability			x
	Validity		x	
	Interoperability	x		
	Technical stability		x	
	Effectiveness/Efficacy/Efficiency	x		
	Accessibility		x	
	Scalability			x
	User experience and usability		x	
	Security			x

Is there a clear process detailing how the assessment framework is to be applied? Please describe.	Framework is advisory applied variously by different organisations NICE is piloting a digital health evaluation process using the framework as a guide to inform internal processes and methods What does the governance look like? The Governance is led by a board made up of a non-executive chair, non-executive members and a chief executive. What processes are defined? The work programme is set by Minister or NHS England in advance of the development of guidance and can take between 6months to 2 years. Decision on which topic to refer to NICE's work programmes are in some case taken following consultation with stakeholders but all programmes are based on NICE's capacity and the quality of evidence available. • Framework when used by NICE follows NICE processes and methods • Assessment is also done by external commissioners and decisionmakers NICE works together with other organization in the heath and care system: Department of Health and Social Care, Office for Life Sciences, NHS England, NHSX, Public Health England, NHS Digital, Health Education England.

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How long does a typical assessment take?	A NICE digital health technology evaluation will take 6-8 months.
Explain the framework's sustainability and business model.	No available information
Presentation and visualization of the assessment results	Website access to: • All NICE technology appraisal outputs and guidance are available on its website along with a range of journals and other evidence-based resources for health and social care staff in England including Healthcare Database (bibliographic databases, evidence-based resources,

Framework Name	Good practice guidelines on health apps and smart devices (2016)
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	The framework aims to provide guidance for, promote use of and increase confidence in health apps and smart devices, by supplying good practice guidelines for manufacturers and evaluators (evaluating bodies, consumer associations or medical professional organisations), who can use them for their own assessments. These guidelines cover apps and smart devices that have no stated medical purpose. In other words, they apply specifically to the "grey area" of apps or smart devices that have potential effects on health but are not medical devices. Medical devices, as defined by European Directive 93/42/EEC which leads to CE marking, are excluded.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*Haute Autorité de Santé* (HAS) https://www.has-sante.fr France
Owner Name *The entity responsible for implementing the framework,*	Haute Autorité de Santé (HAS)

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maintaining and updating it. May be the same entity as the creator.	
Owner Type	Governmental institution / state-run agency
Year of Creation	2016
Website / Web Presence	https://www.has-sante.fr/jcms/c_2681915/en/good-practice-guidelines-on-health-apps-and-smart-devices-mobile-health-or-mhealth
Update Frequency *Is the framework revised and updated periodically? How often?*	No available information
Last Update	No available information
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	International: France and other European countries
Conformity Basis	Voluntary – the use of the framework provides guidance to promote use of and increase confidence in health apps and smart devices.
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Developers Health professionals Researchers These guidelines represent a first step in the processes of evaluating and designing mHealth apps and smart devices. They will be subject to change as the sector develops.

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Assessment Domain Coverage *Which assessment domains does the framework address specifically? Does the framework consider, somewhat considers or does not consider the domains?*	Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
	Privacy	x		
	Transparency	x		
	Safety	x		
	Reliability		x	
	Validity	x		
	Interoperability		x	
	Technical stability		x	
	Effectiveness/Efficacy/Efficiency		x	
	Accessibility		x	
	Scalability		x	
	User experience and usability	x		
	Security	x		
Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The guidelines are intended for self-assessment. The guideline contains five categories and fourteen subcategories. HAS is currently developing a proposal for functional classification of digital solutions on the basis of their purpose. The proposal is in progress with public consultation.			
Explain the framework's sustainability and business model.	No available information			
Presentation and visualization of the assessment results	List of tables			

Framework Name	App Check *DiaDigital* and *PneumoDigital*

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Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	*AppCheck* serves as an information platform that reports everything important about apps and (digital) healthcare. *DiaDigital* helps users evaluate the quality and reliability of diabetes apps whereas *PneumoDigital* helps users evaluate the quality and reliability of Pneumological apps.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*Center for Telematics and Telemedicine GmbH* (ZTG GmbH) https://www.ztg-nrw.de/ Center for Telematics and Telemedicine GmbH (ZTG GmbH Universitätsstrasse 142 Germany
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	*Center for Telematics and Telemedicine GmbH* (ZTG GmbH) https://www.ztg-nrw.de/ Germany
Owner Type	Non-governmental institution, for-profit (limited liability company [KOMM.]) [84]
Year of Creation	*AppCheck* Website: 2012

[84] AppCheck is integrated as an offer by ZTG GmbH in the state initiative eGesundheit.nrw, which is funded by the Ministry of Labor, Health and Social Affairs of the State of North Rhine-Westphalia.

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	Kooperation *DiaDigital* 2016/2017 *PneumoDigital* 2018/2019
Website / Web Presence	https://appcheck.de/bewertung-durch-diadigital-und-pneumodigital/ https://www.diadigital.de/selbstauskunft/ https://www.atemwegsliga.de/pneumodigital.html
Update Frequency *Is the framework revised and updated periodically? How often?*	Regular updates, if new apps have been evaluated or certified. *AppCheck* usually receives new articles weekly
Last Update	No available information
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	International: Germany and other country
Conformity Basis	Voluntary – the use of the framework provides to evaluate the quality and reliability of diabetes and pneumological app, and as secondary benefits provide a list of apps useful to manage diabetes and different conditions related to lungs (asthma, smoking, sleep apnoea, COPD etc.)
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Developers Health professionals Researchers citizen/patients Value proposition The AF gives the possibility to evaluate the quality and reliability of the app and awarded after that a quality seal. Once the quality seal is awarded, the app is included in a list of mobile health apps with remarkable safety and quality. If the developer receives a negative feedback on the potential for improvement, he can apply again.

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Assessment Subject	Health apps (diabetes and pneumological condition) (some of these are certificated as medical apps (European MDR); the belongs to the area of lifestyle and wellness apps.

Assessment Domain Coverage

Which assessment domains does the framework address specifically?

Does the framework consider, somewhat considers or does not consider the domains?

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
Privacy	x		
Transparency	x		
Safety		x	
Reliability			x
Validity			x
Interoperability			x
Technical stability		x	
Effectiveness/Efficacy/Efficiency		x	
Accessibility		x	
Scalability			x
User experience and usability		x	
Security		x	

Is there a clear process detailing how the assessment framework is to be applied? Please describe.

The process includes:

- The app manufacturer requests the seal and completes a self-assessment for the app.
- The *Center for Telematics and Telemedicine* in Bochum (ZTG) carries out a technical review and creates a report.
- The *DiaDigital* or *PneumoDigital* app testers perform the individual evaluation (usability, accessibility, health outcomes).
- In a teleconference in which all testers can participate, it is checked whether the app meets all important criteria. The results of the testers are summarised in a conclusion.
- The app will be published with the self-dissemination, the result of the technical review and the conclusion in the "Certified App" area. If an app does not meet the criteria, the manufacturer receives feedback on the potential for improvement and can then apply it again.

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	ZTG GmbH is responsible for the provision of the *AppCheck* platform and the technical and legal examination Diabetes: *DiaDigital* is responsible for the medical evaluation and testing of usability and accessibility. *DiaDigital* is a merger of German Diabetes Society (DDG) *DiabetesDE* - German Diabetes Help (self-help organisation) *Verband der Diabetes Beratungs- und Schulungsberufe in Deutschland e.V.* (VDBD) Pneumological Apps: *PneumoDigital* is responsible for the medical evaluation and testing of usability and accessibility. *PneumoDigital* is a merger of: *Alpha1 Germany e.V.* *German respiratory league e.V.* *German Patient League Respiratory Diseases e.V.* AF produces a qualitative outcome represented by a final report. The AF includes a quality seal: evaluation app, human assessors vs automatic
How long does a typical assessment take?	Depends on the app; an evaluation period is usually four weeks; within this period the testers can check the app at a freely chosen time; after these four weeks there is a telephone conference
What are the stated benefits of applying the framework? Please relate them to the main target audience(s) identified earlier.	Patients and health professionals are given the opportunity to test mHealth applications without obligation and thus expand their digital health competence; they are informed about current changes in the market at an early stage Patients and healthcare professionals learn which apps are appropriate for their condition and may save them from doing their own research App manufacturers receive qualified feedback on their products and receive a seal of approval that attests to the quality of their apps
Explain the framework's sustainability and business model.	ZTG GmbH is mainly funded by the local government of the region North Rhine-Westphalia. The fees for an *DiaDigital*-Certificate can be found on this website: https://www.diadigital.de/preisuebersicht/ It is an expense allowance; in principle, both certificates are financed by equity or subsidies and there is no classic business model

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Presentation and visualization of the assessment results	searchable app library (website) *AppCheck*: https://appcheck.de/zertifizierte-diabetes-apps-2/ Diabetes/DiaDigital: https://www.diadigital.de/apps-mit-siegel/ Pneumologicalapps/PneumoDigital: https://www.atemwegsliga.de/pneumo-digital-apps.html

Framework Name	eHealth Suisse: mHealth
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	In Switzerland, the cantons are responsible for the health care supply for their population. As people today move around, change doctors or travel to other regions, this means that the needed health information could be missing at the crucial moment. Therefore, eHealth Suisse has been coordinating the design and implementation of the Swiss Electronic Patient Record between the relevant stakeholders. Among these, there are in particular the federal government, cantons, care providers, physicians associations and so on. The Federal Act of 19 June 2015 on the Electronic Patient Record stipulates patients can upload their own data to their Electronic Patient Record (EPR). The objectives of eHealth Suisse for the topic mHealth are: • In order to promote the digitalization in the health care system focusing on the introduction and dissemination of EPR, eHealth Suisse aims at making it possible to primarily patients and also to health professionals to upload data collected by apps into the Swiss EPR. • To contribute to the efficiency, quality, and safety of the healthcare system. To foster a secure use of apps in the context of the Swiss EPR, eHealth Suisse has edited the recommendations: "mHealth - Recommendations I". In order to achieve these aims and based on the above-mentioned recommendations, eHealth Suisse has elaborated the following products: • Guideline focused on the regulatory and legal situation in Switzerland and developed to help distinguish between lifestyle/wellness products and medical devices and to prepare and carry out the certification process.

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	• Criteria catalogue for self-declaration of the quality of health apps created to establish more transparency with regard to the quality of health apps. • Recommendations for the use of technical norms and standards in the field of mHealth • Development of profiles for the technical connection of mHealth-apps to the Swiss EPR (ongoing activity).
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	Swiss Competence and Coordination Centre of the Confederation and the Cantons. Switzerland
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	Swiss Competence and Coordination Centre of the Confederation and the Cantons.
Owner Type	Governmental institution / state-run agency
Year of Creation	2019, not active yet
Website / Web Presence	https://www.e-health-suisse.ch/gemeinschaften-umsetzung/ehealth-aktivitaeten/mhealth.html
Update Frequency *Is the framework revised and updated periodically? How often?*	An update of the guideline for app developers, manufacturers and distributors will be published in August 2020. The criteria catalogue for self-declaration of the quality of health apps has not yet been implemented. However, we assume that we will have to update it - after its implementation - approximately every five years in cooperation with the most important stakeholders in the health care system.
Last Update	24.10.2019

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Geographical Application Scope *Provide a type and name the actual geographical location(s).*	National: Switzerland
Conformity Basis	The profile for the technical connection between an app and the Swiss EPR will become mandatory in the mid-term. The use of the guideline for app developers, manufacturers and distributors is voluntary. The criteria catalogue for self-declaration of the quality of health apps has not yet been implemented. It is not planned to make its use mandatory.
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	• Developers • Health professionals • Researchers • Patient organisations • Patients The criteria catalogue for self-declaration of the quality of health apps: eHealth Suisse developed a list of nine criteria for the self-declaration of the quality of health apps. The list considers the current state of research as well as findings from practical experience and industrial norms, such as international standards for the evaluation of software. In order to ensure the support of manufacturers and the health care system, all relevant stakeholder groups were consulted when defining the criteria. Its aim is to establish more transparency with regard to the quality of health apps for the health professionals, patient organisations, and the patients themselves. Guideline for app developers, manufacturers, and distributors: Its aim is to help app developers, manufacturers, and distributors to distinguish between lifestyle/wellness products and medical devices and to prepare and realize the certification process for apps. The guideline also contains checklists which guide the developers through central questions on how to develop a safe and compliant medical device.

Assessment Domain Coverage	Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider

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Which assessment domains does the framework address specifically? Does the framework consider, somewhat considers or does not consider the domains?			
			None criteria "yes" or "somewhat"
Privacy		x	
Transparency		x	
Safety		x	
Reliability			x
Validity		x	
Interoperability		x	
Technical stability		x	
Effectiveness/Efficacy/Efficiency	x		
Accessibility			x
Scalability			x
User experience and usability			x
Security		x	

Assessment Domain Coverage *Which assessment domains does the framework address specifically? Does the framework consider, somewhat considers or does not consider the domains?*	The catalogue of criteria focuses on nine generic criteria. Professional associations, medical societies and patent organizations can specify what additional information they want to receive from the app developer within the criteria catalogue. Guideline for app developers, manufacturers and distributors is an assistance for developers, manufacturers and distributors and is not used for the assessment of apps.
Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The criteria catalogue for self-declaration of the quality of health apps is presented in the form of nine quality criteria (Transparency, Suitability, risk management, ethical and legal aspects, validity of content, technical suitability, usability, resource efficiency). The strength of the catalogue is that it does not go into too much detail. It has a flexible basic structure able to answer to a highly dynamic market. As the criteria catalogue hasn't been implemented yet the process how it will be applied has to be defined.

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How long does a typical assessment take?	Unknown as the criteria catalogue has not been implemented yet.
What are the stated benefits of applying the framework? Please relate them to the main target audience(s) identified earlier.	The main aim of the criteria catalogue is to create transparency for the app users. So patient organisations or medical societies can check the self-declaration and make recommendations which app is trustworthy. This way health professionals know which apps are trustworthy and can be recommended to their patients. The patient can e.g. rely on the patient organisation's recommendations.
Explain the framework's sustainability and business model.	This will be defined in the mid-term.
Presentation and visualization of the assessment results	Central online database available to all stakeholders and the public (website, mobile device)

Framework Name	MindApps.dk
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	Today there is a lack of control with data security and an absence of common standards for quality, which is one of the major barriers for using apps in treatment for mental health. *MindApps* helps users and therapist choose quality assured apps for mental health. At MindApps.dk you can: • Search for apps for specific target groups and interventions • Read reviews of apps for prevention, treatment, and recovery • Get knowledge about opportunities and limitations using apps for mental health • Get inspiration on how apps can be part of patient-to-therapist collaboration MindApps.dk and the framework "The App Checker" ensure quality in apps.
Creator *The entity or group of entities which created the*	Centre for Telepsychiatry in the Region of Southern Denmark, department in the Psychiatry in the Region of Southern Denmark. Centre for Telepsychiatry, Heden 11, 1. og 3. Sal, 5000 Odense C

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framework. Legal name, website, country and other details.	Telephone 9944 9550 Mail telepsykiatriskcenter@rsyd.dk Denmark
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	Centre for Telepsychiatry in the Region of Southern Denmark
Owner Type	Governmental institution / state-run agency
Year of Creation	2017
Website / Web Presence	https://mindapps.dk
Update Frequency *Is the framework revised and updated periodically? How often?*	The framework is under revision as part of a pilot for a national app guide in Denmark which will be across sectors and besides the psychiatric area.
Last Update	The framework is under its first more substantial revision since the launch in 2017 as part of the national app guide.
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	The app guide is anchored in the Region of Southern Denmark with a national reach
Conformity Basis	Voluntary – the use of the framework provides help, so users and therapists can find quality assured apps for mental health. The framework is available so that you can make the screening by yourself or visit the library of pre-screened apps.

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Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Developers Health professionals Researchers Patients The *MindApps* quality assessment is based on The App Checker and a review process where at least two independent therapists and a data security expert from Centre for Telepsychiatry review the app.
Assessment Subject	Apps for mental health

Assessment Domain Coverage

Which assessment domains does the framework address specifically?

Does the framework consider, somewhat considers or does not consider the domains?

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
Privacy		x	
Transparency			x
Safety		x	
Reliability		x	
Validity			x
Interoperability			x
Technical stability			x
Effectiveness/Efficacy/Efficiency			x
Accessibility			x
Scalability			x
User experience and usability		x	
Security		x	

Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The AF consists in 3 steps: Step 1 in *The App Checker*: Information about the app covering technical specifications, who the developer is, how the app has been developed, target group, language, operating system, price and more. You need this background information in order to decide whether the app is relevant to assess and use. Step 2 in the *App Checker*: Assessment of security and privacy

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The app collects personal data and processes data in a secure manner and the assessment of security and privacy consists of 3 steps starting out with a risk assessment. The risk assessment has 8 levels, R1-R8, and the risk level of the app is decisive for the number of parameters you have to assess. If the risk level is above R1, you will be guided through a decision tree, covering whether or not personal sensitive data is collected, how data is processed and how you as a user can manage your data. If the risk level is above R5, you will also be guided through a decision tree deciding if the app should be CE-marked.

Step 3 in the *App Checker*: Assessment of quality

Now you need to do the final assessment of the quality of the app. This part of the App Checker takes you through 4 categories, each containing 3 questions:

- Background information
- Clinical quality
- Functionality
- Usability

In each question you can rate the app with a score from 1 to 3. In the end The App Checker will calculate an average score. To make this assessment of the quality you need to click through the functions in the app and make yourself familiar with the navigation. If you cannot find the answer to a question you should rate it with 1 point. If a question is irrelevant for the app, rate it with 2 points. It will always be an individual judgement if you think the scores high enough in the categories that are most important to you. Very few app will accomplish an average score of 3 points, and on Mindapps.dk we expect an app to score higher than 1.50 if we are to recommend it.

The process is described overall without a fixed test organization. There is a person responsible for every review that is responsible for finding the right therapists in their psychiatric hospital. The report is then written and uploaded to MindApps.dk internally by the person responsible.

The result is a score and a report where you can read more about the app. Reviewed apps get a score from 0.0 to 3 stars. The score is an average of the points the therapists have given based on The App Checkers 12 questions. The score cannot stand alone and must be seen in context with the rest of the assessment. For example, an app can have excellent background information, clinical quality and design, but if there are some features missing, it will not get 3 stars.

- 3.0 is given to a completely flawless, well-designed and well-written app that is developed with users and has good documentation for effect.
- 2.0 is given to an app with good background information, clinical quality, functionality and design.

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	• 1. 0 is given to an app that has some useful features but is lacking at a level that has a negative effect on the use of the app. You will not find apps with a score lower than 1.5 on MindApps.dk.
How long does a typical assessment take?	For each assessment, new relevant therapists must be found, which often are the longest part of the process, and it varies. The test itself takes 2-3 weeks with two weeks of testing and an interview-based on The App Checker. The preparation of the report and upload takes a couple of days
What are the stated benefits of applying the framework? Please relate them to the main target audience(s) identified earlier.	• Developers Developers have a tool to test their system to make sure it lives up to the standards of apps used in the healthcare sector. • Health professionals Health professionals can find inspiration, specific apps to use in their work, test apps by themselves, and find advice about the use of apps. • Researchers Researchers can find inspiration and find advice about the requirements for apps and their work with developing. • Patients Patients can find inspiration, specific apps to use, test apps by themselves, and find advice about the use of apps.
Explain the framework's sustainability and business model.	Publicly funded framework to support and extend the use of apps across psychiatric care
Presentation and visualization of the assessment results	https://mindapps.dk/ - Main site https://mindapps.dk/en/ - English beta version

Framework Name	PAS 277:2015 Health and wellness apps – Quality criteria across the life cycle – Code of practice
Short Description *What is the purpose of the framework? What does it*	The Publicly Available Specification (PAS) 277:2015 published by the British Standards Institution and sponsored by Innovate UK was mainly created for health and wellness app developers and it encourages the development of highly effective and safe apps. It contains quality criteria and covers the stages of the app life-cycle project, including

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assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.	development, testing, release, and update. The PAS does not contain requirements for apps that are classified as medical devices or are subject to other regulatory matters. PAS 277 is being used as a basis for developing an ISO Technical Specification (ISO/TS 82304-2 under ISO/TC 215).
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	The British Standards Institution / BSI Standards Limited www.bsigroup.com UK
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	The British Standards Institution
Owner Type	Governmental institution / state-run agency
Year of Creation	2015
Website / Web Presence	https://www.bsigroup.com/
Update Frequency *Is the framework revised and updated periodically? How often?*	Periodically: at intervals not exceeding two years
Last Update	No information available
Geographical Application Scope	National: UK

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Provide a type and name the actual geographical location(s).	
Conformity Basis	Voluntary
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Developers Health professionals Researchers Others: providers, charities, and community organizations commissioning bespoke apps The PAS contains a set of quality criteria mainly aimed at guiding app developers throughout an app project life cycle. It can also be used by healthcare professionals, patients and the public to select apps and recommend.
Assessment Subject	Apps for mental health

Assessment Domain Coverage

Which assessment domains does the framework address specifically?

Does the framework consider, somewhat considers or does not consider the domains?

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
Privacy		x	
Transparency		x	
Safety		x	
Reliability		x	
Validity			x
Interoperability		x	
Technical stability		x	
Effectiveness/Efficacy/Efficiency	x		
Accessibility		x	
Scalability		x	
User experience and usability		x	
Security		x	

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Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The PAS contains guidelines for app developers, mainly intended as self-assessment. No experts are involved.
Explain the framework's sustainability and business model.	There are no purchase costs. The development of the guideline was sponsored by Innovate UK. The PAS is currently maintained and updated by the British Standards Institution, which represents the national standards body of the United Kingdom.
Presentation and visualization of the assessment results	none

Framework Name	APPKri
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	The Fraunhofer Institute for Open Communication (FOKUS) has developed a comprehensive meta-catalogue of criteria for evaluating health apps. Stakeholders such as patient associations and medical associations are supported in the systematic evaluation and recommendation of health apps by offering a platform where criteria catalogues suitable for their target groups and objectives can be created. The catalogue can be easily exported from the online platform and further used as a basis for assessing health applications.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	Fraunhofer Institute for Open Communication Systems FOKUS https://www.fokus.fraunhofer.de/ Germany
Owner Name	*Fraunhofer Institute for Open Communication Systems FOKUS*

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The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.	
Owner Type	Non-for-profit Non-governmental institution
Year of Creation	2018
Website / Web Presence	https://ehealth-services.fokus.fraunhofer.de/BMG-APPS/
Update Frequency *Is the framework revised and updated periodically? How often?*	No available information
Last Update	No available information
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	International: Germany, EU-countries, non-EU countries
Conformity Basis	Voluntary
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Medical institutions Self-help groups Health professionals *APPKri* is addressed to medical institutions and self-help groups who want to engage in a systematic evaluation of health apps by allowing them to create specific assessment criteria catalogues.

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Assessment Subject	Health apps in general, medical apps, lifestyle and wellness apps, Health services

Assessment Domain Coverage

Which assessment domains does the framework address specifically? Does the framework consider, somewhat considers or does not consider the domains?

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
Privacy	x		
Transparency	x		
Safety		x	
Reliability		x	
Validity		x	
Interoperability	x		
Technical stability		x	
Effectiveness/Efficacy/Efficiency	x		
Accessibility		x	
Scalability		x	
User experience and usability		x	
Security		x	

Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The creation and editing of the criteria catalogue are performed by the target groups (medical associations, self-help groups etc.) The *APPKri* criteria catalogue contains several hundred criteria available for compiling specific catalogues. The *APPKri* catalogue is divided into two partial catalogues. The first catalogue contains legal requirements which are mapped into *AppKri* as ready-made questionnaires. The second one contains criteria which are not directly attributable to a legal requirement. The creation of catalogues is possible online, via the *APPKri* platform.
Explain the framework's sustainability and business model.	Project funded by the Ministry of Health (BMG)
Presentation and visualization of the assessment results	No available information

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Framework Name	AppQ
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	The *Bertelsmann Stiftung* with the participation of *Fraunhofer FOKUS* has developed the *APPQ* set of quality criteria for digital health apps (DIGA). The development was funded by the German Federal Ministry of Health. *AppQ* aims to serve as a tool for quality transparency through the collection of self-disclosures from developers of health apps. It builds on the knowledge gathered in *APPKRI* and other international efforts.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*The Bertelsmann Stiftung* https://www.bertelsmann-stiftung.de/en/ Germany
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	*The Bertelsmann Stiftung*
Owner Type	Private operating foundation
Year of Creation	2019
Website / Web Presence	appq-kernset.de
Update Frequency	An evaluation and evolutionary concept are in progress. The aim is to update *AppQ* regularly.

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Is the framework revised and updated periodically? How often?	
Last Update	October 2019, current version 1.0 (update 1.1 will be out in July 2020)
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	National: Germany (most of the criteria also work in other German speaking countries)
Conformity Basis	Voluntary
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Policy makers Developers Health professionals Researchers Others: Patients, insured persons Increased exposure for developers and transparency or rather reassurance for users, health professionals, commissioners and other engaged stakeholders.
Assessment Subject	Digital Health Applications (DIGA) with the following characteristics: • It is a digital application, i.e. a native smartphone, tablet or Smartwatch app, a web application or a voice application for voice assistants • The application is subject to the scope of the German Medical Devices Act (MPG) or has a comparable approval by a foreign authority for medical devices, e.g. by the Food and Drug Administration ("FDA approval") • In any case, the application also has an interface for patients, whereby an additional interface is harmless for doctors and other target groups • In any case, the application is also available in German language
Assessment Domain Coverage *Which assessment domains does the*	

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria

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framework address specifically? Does the framework consider, somewhat considers or does not consider the domains?			"yes" or "somewhat"
	Privacy		x	
	Transparency	x		
	Safety		x	
	Reliability		x	
	Validity		x	
	Interoperability	x		
	Technical stability		x	
	Effectiveness/Efficacy/Efficiency	x		
	Accessibility		x	
	Scalability		x	
	User experience and usability	x		
	Security		x	

Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The AppQ core set specifically defines nine subject areas: • Medical quality • Positive supply effects • Data protection • Information security • Technical quality • Consumer protection and fairness • Intraoperality • Usability and motivation • Connection to the health system These nine areas are - in version 1.0 - broken down into 24 criteria and 177 indicators. Developers of health apps use a special web application to provide self-disclosures on the criteria (https://trustedhealthapps.org/publisher). Non-profit and public-law institutions, e.g., medical societies, can use the quality data collected with *AppQ* via a programming interface to make evaluations of health apps. One of the institutions that uses the data to evaluate apps and create quality transparency is the so-called "White List", another project of the Bertelsmann Stiftung. It is being launched in Germany under the label "Trusted Health" and plans to expand into the international arena in the future.
Explain the framework's	The development of the framework was funded by the German Federal Ministry of Health and it is maintained by the Bertelsmann Stiftung, which is a private operating foundation.

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sustainability and business model.	
Presentation and visualization of the assessment results	*AppQ* does not have a repository of its own but other initiatives use the criteria to curate the content added on their website. e.g., The website created by the White List, a project of the Bertelsmann Stiftung, uses the *AppQ* criteria and corresponding data to create quality transparency on the health apps (DIGA) in Germany. The website will be launched in summer 2020: https://trustedhealthapps.org/apps

Framework Name	BfArM DiGA-Fast-Track and Guidance Document
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	*BfArM* offers a summary of the regulations that can be found in the German Social Code Book Five (*Fünftes Buch Sozialgesetzbuch*), in the Digital Health Applications Ordinance (DiGAV) and in the annexes to the *DiGAV*. In the guidance document, the *BfArM* explains how it will regularly interpret the normative specifications of the Social Code Book Five, chapters 33a and 139e, and *DiGAV* within its assessment procedures. It thus offers transparency about the concrete requirements to be fulfilled in the procedure. At the same time, the guide is also designed in a way that all interested parties can have a comprehensive picture of the assessment bases and consequently of the (quality) characteristics of a Digital Health Application (DiGA) [85]. The Guidance will be continuously adapted, supplemented and further developed based on experience gained. The *BfArM* also gives advice on the requirements for inclusion in the *DiGA* directory according to § 139e *SGB* V in order to ensure comprehensive support for applicants and to provide early assistance in

[85] Digital Health Application (DIGA has a wide range of possibilities to support the detection and treatment of diseases and a self-determined, health-promoting lifestyle. It is a medical device with the following characteristic: **1**. Medical device of risk class I or IIa (according to MDR or, within the framework of the transitional regulations, according to MDD); **2.** The main function of DiGA is based on digital technologies; **3**.the medical purpose is essentially achieved by the main digital function; **4**.The DiGA supports the detection, monitoring, treatment or alleviation of diseases or the detection, treatment, alleviation or compensation of injuries or disabilities; **5**.The DiGA is used by the patient or by the service provider and the patient together.

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	generating meaningful documents and data for (final) inclusion, and on procedural issues as well as on questions concerning the notification of essential changes of a *DiGA*. The procedure is designed as a fast track: The evaluation period for the *BfArM* is three months after receipt of the complete application. The core of the procedure is the examination of the manufacturer's information on the required product characteristics - from data protection to user-friendliness - as well as the examination of evidence to be provided by the manufacturer for the positive care effects that can be achieved with *DiGA*.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) / Federal Institute for Drugs and Medical Devices* (BfArM) https://www.bfarm.de/DE/Home/home_node.html Germany
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	*Bundesinstitut für Arzneimittel und Medizinprodukte* (BfArM) / *Federal Institute for Drugs and Medical Devices* (BfArM)
Owner Type	Independent federal higher authority within the portfolio of the Federal Ministry of Health
Year of Creation	2020
Website / Web Presence	https://www.bfarm.de/EN/MedicalDevices/DiGA/_node.html
Update Frequency *Is the framework revised and updated periodically? How often?*	The guidance document will be continuously adapted, supplemented, and further developed based on the experience gained.

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Last Update	DiGA-Leitfaden (version 1.0): 05.05.2020
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	National: Germany, also open for applicants outside Germany
Conformity Basis	Mandatory – part of national legislation
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Main tasks of *BfArM*: licensing, improving the safety of medicinal products detecting and evaluating the risks of medical devices monitoring the legal traffic in narcotic drugs and precursors The most important aim of these activities is to increase the safety of medicinal products as well as medical devices and thus that of the patients. Consequently, the *BfArM* makes a major contribution towards the prevention of risks to public health. In addition, it provides high-quality information for all areas of the health system via Internet. Tasks are provided for: • Manufacturers • Healthcare professionals • Researchers • Healthcare insurances • Patients Authorisation and Registration of Drugs A focus of the work is the authorisation of proprietary medicinal products according to the provisions of the Medicinal Products Act. In this conjunction, the health benefit, i.e., the effectiveness, the safety and the pharmaceutical quality are assessed. In addition, the *BfAr*M fulfils important tasks within the framework of European drug authorisation. Homeopathic drugs are either registered by the *BfArM* without any information regarding possible applications or authorised for specific applications. Medicinal Product Safety (pharmacovigilance) After medicinal products have been used by numerous patients subsequent to authorisation, adverse effects that may not have been evident in previous testing during the course of the clinical trials mandated for the authorisation process can manifest themselves. The

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	BfArM collects and assesses reports on the adverse effects of medicinal products and takes the necessary steps to protect patients. Registering and Assessing Risks Related to Medical Devices Medical devices are instruments, apparatus, appliances, software, substances and preparations made from substances and other objects for medical purposes intended by their manufacturers for human use, e.g., x-ray machines, cardiac pacemakers, artificial hip replacements, bandages, infusion equipment, catheters, optical aids, condoms, medical instruments and laboratory diagnostics. The main tasks of the *BfArM* involve the central collection, analysis and assessment of risks resulting from the application or use of medical devices and in coordinating any measures that must be taken. In this conjunction, it relies on the reports it receives regarding incidents with medicinal products. Narcotics and Precursors The Federal Opium Agency, which is responsible for granting licenses to legally trade in narcotic drugs and precursors (i.e., for the production of substances suited for use as narcotics) as well as for overseeing their production, cultivation and sale as imports as well as exports is also part of the Federal Institute for Drugs and Medical Devices. It cooperates with international institutions to monitor trade in narcotics.
Assessment Subject	Digital Health Application (DIGA) has a wide range of possibilities to support the detection and treatment of diseases and a self-determined, health-promoting lifestyle. It is a medical device with the following characteristics: 1. Medical device of risk class I or IIa (according to MDR or, within the framework of the transitional regulations, according to MDD); 2. The main function of *DiGA* is based on digital technologies; 3. The medical purpose is essentially achieved by the main digital function; 4.The *DiGA* supports the detection, monitoring, treatment or alleviation of diseases or the detection, treatment, alleviation or compensation of injuries or disabilities; 5 The *DiGA* is used by the patient or by the service provider and the patient together.
Assessment Domain Coverage *Which assessment domains does the*	Domain / Considers >65% criteria "yes" / Somewhat considers The rest / Does not consider None criteria

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framework address specifically? Does the framework consider, somewhat considers or does not consider the domains?			"yes" or "somewhat"
	Privacy		x	
	Transparency	x		
	Safety		x	
	Reliability			x
	Validity		x	
	Interoperability	x		
	Technical stability		x	
	Effectiveness/Efficacy/Efficiency	x		
	Accessibility	x		
	Scalability			x
	User experience and usability		x	
	Security		x	
Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The procedure is designed as a fast track: The core of the procedure is the examination of the manufacturer's information on the required product characteristics - from data protection to user-friendliness - as well as the examination of evidence to be provided by the manufacturer for the positive care effects that can be achieved with *DiGA*. Applications for listing in the *DIGA* directory according to § 139e *SGB V* are to be submitted exclusively electronically via an application portal What aspects are defined? Safety and functionality, Data protection, Information Security, Interoperability How long does a typical assessment take? The evaluation period for the *BfArM* is three months after receipt of the complete application What is the assessment outcome – qualitative, quantitative (e.g. score) and how is it to be interpreted? The outcome is qualitative.		
How is the assessment performed?	The Fast-Track assessment of *DiGA* consists of two major elements - the proof of defined requirements and the proof of a positive care effect. The time frame for the fast-track assessment is 3 months. According to the *DiGAV, DiGA* manufacturers have to demonstrate defined requirements in the areas of safety, functional capability, data protection and information security, as well as interoperability and		

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	quality to the *BfArM*. This is mainly done by the proof of legal medical device requirements and completing checklists by applicant of the *DiGA*. In terms of e.g., medical content of the *DiGA* it must derive from accepted and reliable sources such as medical guidelines, established textbooks or at least comparable recognised sources such as published studies. The relevant references have to be pointed out to the *BfArM* in a bibliography by the applicant. If a *DiGA* pursues a new approach to care with no publications available yet, the quality of content will be clarified in individual cases. Advice from the *BfArM* in the advance to the application is recommended. Furthermore, *DiGA* applicants have to proof a positive care effect in order to become listed in the *DiGA* directory. This proof has to be based on at least a retrospective study comparing the standard of care against the *DiGA.* Thus, the positive care effect has to be proven either in the German care context or it has to be demonstrated why the care setting is comparable to Germany. A positive care effect can either be a medical benefit, such as an improvement of patient-relevant endpoints or based on patient-relevant structural or procedural improvements (e.g., patient safety, adherence or improvement in access to care). The evidence provided by the applicants is examined by the *BfArM* in order to assess a possible positive care effect. If the application to the *DiGA* directory is preliminary *BfArM* assesses first systematic data provided by the manufacturer and an evaluation concept, which has to be prepared by a manufacturer independent institution.
Explain the framework's sustainability and business model.	The *BfArM* is a higher competent authority and research institute of the German Federal Government which conducts its own as well as independent research in order to fulfil its tasks pursuant to Section 4 sub-section 3 BGA successor legislation. The *BfArM's* tasks serve both public health as well as the safety of medicinal products, narcotics, and medical devices. As a federal institute, the *BfArM* fulfils sovereign tasks without economic purpose (i.e. without the intention of making a profit). Revenue and expenditure of the BfArM are described in Chapter 1510 of the Federal Budget; the sound budgetary management is monitored by the Federal Ministry of Health (*Bundesministerium für Gesundheit, BMG*) and the Federal Audit Office (*Bundesrechnungshof*). The revenue mainly results from fees charged for official acts. Additional revenues are from mandates assigned by the European Medicines Agency EMA and other healthcare institutions. The *BfArM* does not engage in any promotion and has no income based on advertising.

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Presentation and visualization of the assessment results	The DIGA online-directory according to § 139e *SGB V* will be published from August/September 2020 at the *BfArM* website (www.bfarm.de/diga).

Framework Name	GGD AppStore
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	The purpose of the GGD AppStore is to provide an understandable and transparent overview of relevant and reliable health apps and websites. Apps are included in the store after a careful, independent and transparent assessment by expert GGD professionals.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	The Association of Regional Public Health Services (GGD) and Regional Medical Emergency Preparedness and Planning (GHOR) Netherlands https://ggdghor.nl/
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	*GGD-GHOR* Netherlands
Owner Type	Governmental institution / state-run organisation
Year of Creation	2016

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Website / Web Presence	https://www.ggdappstore.nl/
Update Frequency *Is the framework revised and updated periodically? How often?*	No available information
Last Update	No available information
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	National: The Netherlands
Conformity Basis	Voluntary
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Developers Health professionals Citizens The purpose of the website is to provide accurate and trustworthy information for the citizens and all interested parties.
Assessment Subject	The health and wellness apps and websites are published on the website under different categories: -Body functions -Mental well-being -Meaning -Quality of life -Participate -Daily functioning

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Assessment Domain Coverage *Which assessment domains does the framework address specifically? Does the framework consider, somewhat considers or does not consider the domains?*	Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
	Privacy		x	
	Transparency		x	
	Safety			x
	Reliability		x	
	Validity		x	
	Interoperability			x
	Technical stability		x	
	Effectiveness/Efficacy/Efficiency		x	
	Accessibility		x	
	Scalability			x
	User experience and usability		x	
	Security		x	
Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The assessment is carried out by expert *GGD* professionals from all 25 associations. The assessment framework is adjusted on the basis of reactions and new (scientific) insights. The apps and websites are assessed for usability, functionality, privacy, reliability, and effectiveness.			
Explain the framework's sustainability and business model.	No available information			
Presentation and visualization of the assessment results	The assessed apps are included on the website database together with the ratings, a concise review (available in Dutch) and a recognizable vignette. https://www.ggdappstore.nl/			

Framework Name	ORCHA Review Process

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Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	Designed by a multidisciplinary team of subject matter experts and clinicians, the *ORCHA* Review delivers robust, rapid and reliable accreditation for Digital Health worldwide. The *ORCHA* AF has been developed with a core team of Digital Health 'subject matter experts' both clinical and none clinical and has been evaluated in practice by hundreds of health and care systems, organisations and individuals. Its baseline review assesses over 300 criteria, looking for compliance across Professional Assurance, Data Privacy, and Usability/ Accessibility: covering many international policies, regulations, and standards. The *ORCHA* Review is dynamic and responds to the focus area and functionality of an app to assess only the relevant compliance issues. One example of this is in the area of regulation. The number of regulations that an app falls under the scope of, can differ markedly, with relatively simple 'wellbeing' focused Apps triggering relatively few regulatory burdens versus a sophisticated, condition focused App that is likely to trigger significantly more. It is crucial that an assessment approach can cater effectively for this variation. Also, the platform enables *ORCHA* to efficiently carry out a "re-review" of an app after every update. *ORCHA*'s framework can also deliver enhanced reviews, covering more than 500 criteria and 5 areas, including financial and commercial stability, and bespoke adaptations for a specific Country's national programme requirements. Because of the structure of the AF and *ORCHA*'s professional review team, each review requires only 3-4 man-days to conduct. *ORCHA* is able to conduct hundreds of reviews every week, across more than 180 condition and category areas. The have evaluated c5,000 apps to date. *ORCHA* reviews its criteria with international experts every quarter. It is currently conducting a system-wide review with *NeLL*. The app reviews are housed on a platform that can be intelligently searched to find apps against a range of criteria. The platform enables bespoke app libraries to be quick and easily built for clients. *ORCHA* also offers a range of products that can be added to a library, helping professionals to recommend and distribute apps safely to patients, and providing usage insights and measurement. *ORCHA* conducts reviews for government organisations across Europe, the Middle East, and Australasia. In the UK, *ORCHA* conducts reviews for NHS Digital and NHS providers in 50% of regions. NHS England is accelerating adoption across the NHS, placing *ORCHA* in its National Innovation Accelerator Programme. *ORCHA* invests considerable sums in ongoing research on Digital Health compliance and assessment approaches including a major 18 month-long research project co-funded by UK government on User Experience analysis. Thus, *ORCHA* invests back into the mHealth community in the form of research. They support many international initiatives such as the

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	ISI-82304 working group and welcome moves to bring greater consistency to Digital Health Assessment processes. *ORCHA*'s AF has been developed over the past 5 years and has undergone many iterations. The 6th version of the OBR is currently available and the ERC's have evolved from extensive use in the NHS Digital 'DAQ' assessments to fill gaps and improve assessment capabilities.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*Organisation for the Review of Care and Health Applications* (ORCHA) ORCHA Health Ltd UK & the Netherlands https://www.orcha.co.uk
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	*ORCHA*
Owner Type	For profit non-governmental institution
Year of Creation	2015
Website / Web Presence	https://www.orcha.co.uk/our-solution/the-orcha-review/
Update Frequency *Is the framework revised and updated periodically? How often?*	Update (on average) every 9 months.
Last Update	going Live in Autumn 2020 (Version 6)

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Geographical Application Scope *Provide a type and name the actual geographical location(s).*	International: The UK and the Republic of Ireland, the Netherlands, Finland, Sweden, Denmark, Iceland, Norway, New Zealand, Australia, Germany, Canada, and Israel.
Conformity Basis	Voluntary – the use of the framework provides some secondary benefits, such as exposure, addition to a curated library, etc.
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	International Health and Care bodies National Health and care bodies Health and care service providers Health and care professionals App Developers Teachers and Students Charities Employers International Health and Care bodies As a leading Digital Health advisor, *ORCHA* provides consultancy into international Digital Health programmes. *National Health and care bodies: ORCHA* helps governments develop and deliver national health app accreditation programmes. From market insight reports, to full implementation roll-out plans, *ORCHA* helps governments safely adopt digital health and embed into their health services. *Health and Care service providers: ORCHA* helps health and care organisations across Europe, the Middle East, and Australasia, to choose and deliver health apps that will safely make the biggest impact in terms of improving outcomes. Its tools help health and care professionals to recommend and monitor usage of health and care apps. They are proven to increase take-up and self-management of conditions. *ORCHA*'s app review, accreditation, curation and prescription services help national bodies and health service providers to join the journey of integrating quality assured digital health into their care pathways, creating care that is more efficient and patient-centred. It collaborates with national health bodies and health service providers everywhere from Norway to New Zealand. *ORCHA*'s services have been recently approved on the UK Government's Digital Marketplace G-cloud 11 framework and they can be purchased by the public sector. *Health and care professionals:* it offers products for health and care professionals, including an App Library Pro Account, help professionals to recommend quality assured digital health solutions directly to their

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	patients and service users. It is easy for professionals to search its App Library, full of thousands of health and care apps reviewed by *ORCHA*, to either learn about apps for different health conditions, or to find the most relevant apps to recommend to their patients. *App Developers: ORCHA* conducts independent reviews of developers' health and care apps, including web-based apps, and provides them with a score which is shared on our App Libraries, allowing their app to reach their prospective customers. Developers also receive a report to inform product development, which *ORCHA* is uniquely placed to advise on. The reviewed apps are added to the *ORCHA* Health App Repository, "Your health app finder". Furthermore, if the app exceeds *ORCHA*'s 65% quality threshold, the app receives a badge which can be used on their website and marketing materials. *Teachers and Students: ORCHA* developed the 'Digital Healthy Schools Programme', which aims to train young people in mobile health. Digital Healthy Schools is an exciting initiative that local councils commission, to empower young people to embrace and responsibly use apps to support their own health and wellbeing. This is a free resource for schools, and includes access to a customizable Digital Health Hub, lesson plans, assembly PowerPoints and downloadable resources. *Charities: ORCHA* created targeted solutions to activate charity members to search for safe and optimal health and care apps, helping to support both their staff and the people they help. *Employees: ORCHA* developed a variety of services and products to stimulate employees to use health and care apps for condition management and wellness purposes.
Assessment Subject	Health apps, medical apps, lifestyle and wellness apps
Assessment Domain Coverage *Which assessment domains does the framework address specifically?* *Does the framework consider, somewhat considers or does not consider the domains?*	

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
Privacy	x		
Transparency	x		
Safety		x	
Reliability		x	
Validity		x	
Interoperability		x	

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	Technical stability	x		
	Effectiveness/Efficacy/Efficiency	x		
	Accessibility		x	
	Scalability		x	
	User experience and usability		x	
	Security		x	

Is there a clear process detailing how the assessment framework is to be applied? Please describe.

The reviews are performed by reviewers recruited and trained by *ORCHA*. The questions of the assessment are developed by the Review Development Team. The average time to conclude an OBR which is 2 hrs and a full Enhanced Review would be 2-3 days.

The review consists of seven stages:

1. Exclusion filters – weekly analysis of Apps available on the *App Store / Google play* in the "Health, wellbeing / fitness and medical section", with filtering out by certain criteria. The remaining apps are sorted in 350 categories and queued within the category by most downloaded.
2. Levels - The *ORCHA* App Classification system categorises Apps according to their area of focus and the functional capabilities. There are 5 Levels (0-4), each with different areas of investigation and a different review process. The higher the level, the more detailed the review process is.
   - Level 0 – Simple Wellbeing
   - Level 1 – Advanced Wellbeing
   - Level 2- General Health
   - Level 3 – Condition Management
   - Level 4 – Regulated
3. Functions – over 14 functionality features regularly checked for and constantly updated as the apps develop new features and functions.
4. Review Domains - compliance with standards, guidance and best practice in three distinct domains. The domains covered by the reviewers are Data and Security, Clinical Assurance and User Experience. Each of the domains consists of a series of objective (Yes / No) questions which could theoretically be answered by the reviewers from information found in the App, App store or on the supporting website.
5. The score - The analysis results in an overall *ORCHA* score based on the answers to each of the questions in the three review domains. The questions can be given positive or negative points. The score is quantitative (e.g., 65%).
6. Developer notification and publication – developers are notified by the reviewers and can preview the results.

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	7. Post publication review monitoring – reviews remain valid until a new version of the App is produced. Is a new version is not released within 18 months, the app is marked as 'out of date' and the *ORCHA* App Score will be lowered at a rate of 5% per month. If a new version is released, it will go back into the queue for a re-review.
Explain the framework's sustainability and business model.	*ORCHA* generates revenue through app libraries and professional platforms for clinicians. *ORCHA* also receives moderate fees for the independent reviews. The *ORCHA* Fast Track Review allows developers to have their app included in the review schedule and apps with low download numbers to have increased exposure. It assesses over 300 review elements in the three core review domains: Data and Privacy, Professional assurance, and Usability and Accessibility. ORCHA offers a detailed improvement report and a consultation with the review team to discuss the review conclusions. [£499 + VAT] The Prelaunch Review costs £678 +VAT. This type of review enables developers to have their app reviewed if the app has not been yet published or a new version is about to be released. The review offers a detailed improvement report and a consultation with the review team to discuss the review conclusions. *ORCHA* Consult, following Review or Pre-Launch Review: *ORCHA* Consultation Package £149 +VAT charged hourly: it provides innovators with an opportunity to discuss the findings of the review with a member of the team at *ORCHA*. Developers can then choose to make changes and request a re-review (within 8 weeks of the original review) before their app review is included on the ORCHA Microsites. *ORCHA* Consultation Package fees starting at £600 +VAT per day - *ORCHA* can provide access to a range of subject matter experts to support your bespoke requirements. Examples of support include access to experts in Health Economics, Clinical Evidence, Creating value propositions, Business modelling, Data Security Regulations, Data privacy Regulations, Medical Device Regulations, and Clinical Safety. *ORCHA* provides Digital Health Portals (Libraries, Catalogues and Formularies) containing the results of the OBR, to charities for free.
Presentation and visualization of the assessment results	Apps are added to the *ORCHA* repository together with the assessment score. If an app exceeds 65% quality threshold, the app receives a badge which can be used on the website and marketing material. You can view the *ORCHA* App library here: https://appfinder.orcha.co.uk/

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Framework Name	My Health Apps
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	My Health Apps is a website which curates hundreds of health apps tried and recommended by patients and health consumers worldwide. Launched in 2013, it was created and currently being maintained by PatientView. PatientView was a member of the EU Working Group on mHealth Assessment Guidelines.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*PatientView* http://www.patient-view.com/ UK
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	*PatientView*
Owner Type	For profit non-governmental institution
Year of Creation	2013
Website / Web Presence	http://myhealthapps.net/
Update Frequency	No available information

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<table>
<tr><td>Is the framework revised and updated periodically? How often?</td><td></td></tr>
<tr><td>Last Update</td><td>No available information</td></tr>
<tr><td>Geographical Application Scope
Provide a type and name the actual geographical location(s).</td><td>International: UK and other countries</td></tr>
<tr><td>Conformity Basis</td><td>Voluntary – the use of the framework provides some secondary benefits, such as exposure, addition to a curated library, etc.</td></tr>
<tr><td>Target Audience(s) and Value Propositions
List the main target audiences and elaborate the value the framework offers to them.</td><td>Policy makers
Developers
Health professionals
Healthcare communities, including empowered consumers, patients, carers, patient groups, charities and other not-for-profit organisations

The assessed apps are included into the My Health Apps repository, increasing their exposure. The repository is also useful for healthcare communities, professionals and other target groups as it provides a list of curated apps.</td></tr>
<tr><td>Assessment Subject</td><td>Health apps in general, medical apps, lifestyle and wellness apps</td></tr>
<tr><td>Assessment Domain Coverage
Which assessment domains does the framework address specifically?
Does the framework consider, somewhat considers or does</td><td>
<table>
<tr><th>Domain</th><th>Considers
>65% criteria “yes”</th><th>Somewhat considers
The rest</th><th>Does not consider
None criteria “yes” or “somewhat”</th></tr>
<tr><td>Privacy</td><td></td><td>x</td><td></td></tr>
<tr><td>Transparency</td><td></td><td>x</td><td></td></tr>
<tr><td>Safety</td><td></td><td>x</td><td></td></tr>
<tr><td>Reliability</td><td></td><td></td><td>x</td></tr>
<tr><td>Validity</td><td></td><td></td><td>x</td></tr>
</table>
</td></tr>
</table>

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not consider the domains?	Interoperability		x	
	Technical stability			x
	Effectiveness/Efficacy/Efficiency		x	
	Accessibility			x
	Scalability			x
	User experience and usability		x	
	Security			x
Is there a clear process detailing how the assessment framework is to be applied? Please describe.	In the first stage, the assessment is performed either by the developer (self-assessment) or by the users or healthcare communities who want to include an app in the My Health Apps repository. To submit an app, an online survey available in multiple languages must be filled in. Further, background checks are being carried out by PatientView. The background checks include information such as pricing, authenticity of the patient group / empowered consumer submitting the app, the contact details and the geographic location of the app developer, information on the funders of the app and on any medical advisers involved in the making of the app. The approved apps are sorted into three main categories: • Disability • Health, wellness and care in the community • Medical apps			
Explain the framework's sustainability and business model.	The website is maintained by PatientView.			
Presentation and visualization of the assessment results	The apps are included in the My Health Apps repository. https://myhealthapps.net			

Framework Name	CEN-ISO/DTS 82304-2 "Health and wellness apps - Quality and reliability criteria across the life cycle"
Short Description *What is the purpose of the framework? What does it*	The Technical Specification for 'Quality and reliability for health and wellness apps" aims to help establish a common international framework for evaluation of health and wellness apps. It defines quality and reliability criteria to support app developers to design better apps and provides users, including consumers, health professionals, payers

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assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.	and app stores, with a health app quality label inspired by the successful EU Energy label and first- and third-party quality requirements conformity assessment, to enable informed decisions. The scoring mechanism spans healthy and safe, easy to use, secure data and robust build. It builds upon existing international initiatives, ISO, IEC, HL7 and several other standards.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	The Technical Specification is being developed by the European standardisation committee CEN/TC 251 Health Informatics in collaboration with ISO and IEC. The project team includes experts from 14 countries: Australia, Belgium, China, Finland, France, Germany, Ireland, Italy, Japan, Netherlands, Nigeria, Sweden, United Kingdom, and United States.
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	The European standardisation committee CEN/TC 251 Health Informatics CEN/TC 251 WG2. The International Organization for Standardization's Technical Committee on Health Informatics ISO/TC 215 JWG7.
Owner Type	Standards organization
Year of Creation	Currently in preparation, due to be completed in 2020.
Website / Web Presence	https://www.nen.nl/Standardization/Health-and-wellness-apps.htm http://www.ehealth-standards.eu/ https://www.iso.org/home.html
Update Frequency *Is the framework revised and updated periodically? How often?*	Periodic review every 3 years and on demand prior to that.
Last Update	The framework is currently being developed and tested.

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Geographical Application Scope *Provide a type and name the actual geographical location(s).*	International: worldwide.
Conformity Basis	Voluntary
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Users Health professionals Payers Developers App assessors, app stores and repositories Policy makers Researchers CEN-ISO/DTS 82304-2 "Quality and reliability for health and wellness apps aims to help establish a common international framework for evaluation of health and wellness apps. It builds upon and expands the PAS 277 to meet global requirements. It aims to provide app developers guidance. The quality label and quality report enable users, health professionals and payers to make informed decisions. The common principles and third- party app assessment facilitate accelerated uptake of health apps in line with the EU Digital Single Market transformation of health and care.
Assessment Subject	Health and wellness apps, maintained along other CEN/ISO standards for health software.

Assessment Domain Coverage

Which assessment domains does the framework address specifically?

Does the framework consider, somewhat considers or does not consider the domains?

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
Privacy	x		
Transparency	x		
Safety		x	
Reliability		x	
Validity	x		
Interoperability	x		
Technical stability	x		

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	Effectiveness/Efficacy/Efficiency	x		
	Accessibility	x		
	Scalability		x	
	User experience and usability		x	
	Security		x	
Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The quality requirements conformity assessment includes a maximum of 82 mostly yes/no questions and requests to provide evidence related to: • Product information • Healthy and safe (health requirements, health risks, ethics, health benefits, societal benefits) • Easy to use (accessibility, usability) • Secure data (privacy, security) • Robust build (technical robustness, interoperability) The evidence enables third party app assessment. The resulting health app quality label visualizes quality and reliability in healthy and safe, easy to use, secure data and robust build on a scale from A (dark green) to E (red).			
Explain the framework's sustainability and business model.	Project supported and financed by the European Commission. The specifications are maintained by CEN in collaboration with ISO.			
Presentation and visualization of the assessment results	Health app quality label inspired by the EU Energy label.			

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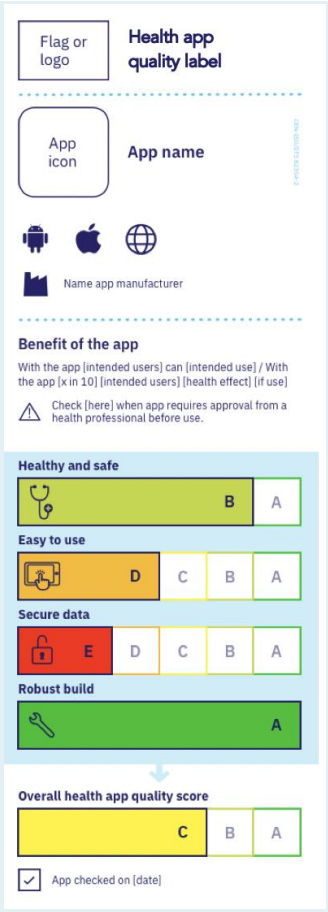

Framework Name	Isys Score
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	*Isys Score* is an evaluation framework for mobile health applications developed by the *iSYS* foundation, a Spanish organization which aims to promote projects related to health and technology. Evaluation focuses on three quality indicators: popular interest, trust, and utility. The framework was created based on a systematic evidence approach, built with a Delphi process. The *iSYS* foundation publishes every year a catalogue as result of analysis approximately 300 medical Apps -that have a Spanish or Catalan version-, and they prepare a collection with the approximately 50 best apps according to the *iSYS* score.
Creator	*iSYS Foundation*

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The entity or group of entities which created the framework. Legal name, website, country and other details.	Barcelona, Spain https://www.fundacionisys.org/es/
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	*iSYS Foundation*
Owner Type	Non-profit non-governmental institution
Year of Creation	
Website / Web Presence	https://www.fundacionisys.org
Update Frequency *Is the framework revised and updated periodically? How often?*	Annually. Currently seven collections have been presented
Last Update	2020
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	International: Spanish / Catalan speaking countries
Conformity Basis	Voluntary – the use of the framework provides some secondary benefits, such as exposure, addition to a curated library, etc.

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	The goal is to recommend good medical apps and help people select them on platforms. Apps are included through 4 procedures. 1. The first, and most relevant, is by searching for the 10 best results offered by Google, by ICD-10 category (14 categories), which represents a total of 140 Apple Store apps and 140 Google play apps (total 280 Apps captured every December). Those that exceed the inclusion criteria are selected below. 2. The second is on the recommendation of patient associations. Every year, a group of 30-40 patient associations are consulted to make their recommendation. 3. The third is to re-evaluate the top 5 from the previous year. 4. Finally, the registration of those Apps that exceed the inclusion criteria is accepted.
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Developers Health professionals Users Assessed apps that exceed a minimum score on the *ISYScore* scale are included in the *iSYS* catalogue, renewed yearly.
Assessment Subject	Apps need to fulfil certain criteria: • Theme: Health and Medicine. • Target audience: patients or healthcare professionals. • Language: Spanish and Catalan. • If they are part of a healthcare process, the necessary accreditation. • More than 500 downloads. • Last update: the year before the collection
Assessment Domain Coverage *Which assessment domains does the framework address specifically?* *Does the framework consider,*	

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
Privacy		x	
Transparency			x
Safety		x	
Reliability			x

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somewhat considers or does not consider the domains?	Validity		x	
	Interoperability			x
	Technical stability			x
	Effectiveness/Efficacy/Efficiency		x	
	Accessibility			x
	Scalability			x
	User experience and usability			x
	Security			x

Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The *iSYS* score rates apps according to three dimensions. Each dimension contains several questions which are graded a certain number of points: *iSYScore Patients* 1. Popular interest -maximum 11 points 2. Confidence – maximum 18 points 3. Utility – maximum 18 points *iSYScore Professionals* 1. Popular interest -maximum 9 points 2. Confidence – maximum 31 points 3. Utility – maximum 28 points The assessment is performed by the *iSYS* foundation designated experts.
Explain the framework's sustainability and business model.	The foundation perceives fees for the assessment and inclusion of the app in the health catalogue. • Individuals: € 75 • SMEs with less than 5 years of experience: € 250 • Already established companies / Large companies: € 500 • Certain non-profit entities, such as civil associations, will receive a 50% discount.
Presentation and visualization of the assessment results	The assessed apps are included in the iSYS health catalogue. For an app to be included in the catalogue, it needs to exceed a minimum score on the ISYScore scale. https://www.fundacionisys.org/es/apps-de-salud/catalogo-de-apps (Spanish / Catalan, no English version)

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Framework Name	Medappcare Quality Approach
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	Medappcare is the certifying body for connected well-being accredited by the French Accreditation Committee (COFRAC), the national accreditation body designated by the public authorities. Medappcare assesses and certifies mobile applications and websites in the areas of health, disability, loss of autonomy, and animal health. The certification highlights the quality of innovative services in these new sectors.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*Medappcare* France http://http//medappcare.com
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	*DEKRA Group* France www.dekra-certification.fr
Owner Type	Non for profit non-governmental institution
Year of Creation	2012
Website / Web Presence	https://www.medappcare.com/en/
Update Frequency *Is the framework revised and updated*	No available information

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<table>
<tr><td>periodically? How often?</td><td></td></tr>
<tr><td>Last Update</td><td>No available information</td></tr>
<tr><td>Geographical Application Scope
Provide a type and name the actual geographical location(s).</td><td>International: French speaking countries</td></tr>
<tr><td>Conformity Basis</td><td>Voluntary – the use of the framework provides some secondary benefits, such as exposure, addition to a curated library, etc.</td></tr>
<tr><td>Target Audience(s) and Value Propositions
List the main target audiences and elaborate the value the framework offers to them.</td><td>• Policy makers
• Developers
• Health professionals
• Researchers
• Users
Medappcare certification provides several benefits:
• to differentiate itself from its competitors, particularly in a bloated market
• reassure its general public and professional users
• to enhance the quality of its services and gain visibility
• to structure its approach thanks to the evaluation report
• to lend credibility to its approach with financial partners and investors</td></tr>
<tr><td>Assessment Subject</td><td>Mobile apps and websites in the areas of health, disability, loss of autonomy, and animal health</td></tr>
<tr><td>Assessment Domain Coverage
Which assessment domains does the framework address specifically?
Does the framework consider, somewhat considers or does</td><td>
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<tr><td>Validity</td><td></td><td></td><td>x</td></tr>
</table>
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</table>

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not consider the domains?	Interoperability			x
	Technical stability		x	
	Effectiveness/Efficacy/Efficiency		x	
	Accessibility			x
	Scalability			x
	User experience and usability			x
	Security		x	
Is there a clear process detailing how the assessment framework is to be applied? Please describe.	The evaluation process includes several steps: 1. Submission of the app – publishers / developers register on the *Medappcare* website 2. Application approval – *Medappcare* reviews the request, ensuring that the provided information is sufficient to carry out the certification process, the developers are aware of all the requirements and that the certification is feasible 3. Getting in contact – if the application is pre-approved, additional information is requested from the app developer 4. General evaluation 5. Medical evaluation – performed by medical evaluators against a medical assessment framework. It includes analysis of the content, the offered service, usage and a panel of criteria specific to the type of app evaluated. 6. Technical evaluation – the developer code is assessed using a technical assessment framework. It includes three main themes: health data protection and payment information, overall performance of app security. 7. Assessment result – *Medappcare* score is generated 8. Evaluation report – a *Medappcare* evaluation report is provided, along with recommendations to improve services 9. *Medappcare* app selection (database) –based on the developer approval and *Medappcare* score, the application can be part of *Medappcare* selection of best apps only accessible to the industrial subscribers.			
Explain the framework's sustainability and business model.	A fee is perceived for the *Medappcare* certification process. Besides certification, *Medappcare* offers trainings and workshops.			
Presentation and visualization of the assessment results	No available information			

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Framework Name	Our Mobile Health
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	*Our Mobile Health* is enabling healthcare professionals to recommend and deploy healthcare apps with confidence. *Our Mobile Health* (OMH) has helped develop an industry leading App Review Process which rigorously examines apps against ten key areas to identify the 'best of the best' apps which are then added to the OMH curated app library. They focus on: • Providing access to mHealth apps that people can trust • Forming partnerships that maximise the reach of our curated digital health app library • Working with healthcare organisations to drive adoption of mHealth apps • Building up the evidence base for health app use • Influencing the mHealth policy environment to bring about sustainable change
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*Our Mobile Health*, London SW6 6NP United Kingdom https://www.ourmobilehealth.com/
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	*Our Mobile Health*
Owner Type	For-profit non-governmental institution
Year of Creation	2013
Website / Web Presence	https://www.ourmobilehealth.com/
Update Frequency	No available information

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Is the framework revised and updated periodically? How often?	
Last Update	No available information
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	National: UK
Conformity Basis	Voluntary – the use of the framework provides some secondary benefits, such as exposure, addition to a curated library, etc.
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	Policy makers Developers Health professionals Researchers Healthcare organization Government organization Charities App Library: The Our Mobile Health curated app library contains only apps that have been through their process and met their rigorous review criteria, meaning healthcare professionals and patients can use them with confidence.
Assessment Subject	Health apps in general, medical apps, lifestyle and wellness apps, Health services
Assessment Domain Coverage *Which assessment domains does the framework address specifically?* *Does the framework consider, somewhat*	

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
Privacy		x	
Transparency			x
Safety		x	
Reliability			x

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considers or does not consider the domains?	Validity			x
	Interoperability		x	
	Technical stability		x	
	Effectiveness/Efficacy/Efficiency		x	
	Accessibility		x	
	Scalability			x
	User experience and usability		x	
	Security		x	
Is there a clear process detailing how the assessment framework is to be applied? Please describe.	Once you've applied for assessment, you must complete an in-depth self-assessment questionnaire, covering areas including technical stability, interoperability, privacy policies, patient safety, usability and regulations amongst others. This allows us to complete a thorough review of all aspects of your health app or digital health service. Once you've submitted your answers, we review your questionnaire. We have access to over 150 clinical experts in various fields, including safety and technical experts, who review your answers. We will provide you with feedback on what changes and improvements, if any, are required. Once any updates are made by your teams, we will review those areas once again and once it meets all necessary requirements we will add your health app or digital health service to our curated library, ready for deployment to healthcare organisations.			
Explain the framework's sustainability and business model.	Our Mobile Health perceives fees for the offered services.			
Presentation and visualization of the assessment results	The assessed apps which fulfilled the criteria for certification are included in the *Our Mobile Health* curated app library.			

Framework Name	cMHAFF: Consumer Mobile Health Application Functional Framework
Short Description	The primary goals of *cMHAFF* are to provide a standard against which a mobile app's foundational characteristics -- including but not limited to

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What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.	security, privacy, data access, data export, and transparency/disclosure of conditions -- can be assessed. Target: Quality Reporting Agencies Regulatory Agency Standards Development Organizations (SDOs) Mobile Health App Developers EHR, PHR Vendors Health Care IT Vendors Local and State Departments of Health Healthcare Institutions (hospitals, long term care, home care, mental health)
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*Health Level Seven International* (HL7) USA http://www.hl7.org/index.cfm
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	*Health Level Seven International* (HL7)
Owner Type	Standards Development Organization (ANSI accredited); Non-governmental institution: Non-for-profit

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Year of Creation	2018
Website / Web Presence	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=476
Update Frequency *Is the framework revised and updated periodically? How often?*	Updated as per *HL7 & ANSI* guidelines Current release: STU: Standards for Trial Use
Last Update	June 2020
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	International: USA and other countries
Conformity Basis	Voluntary – the use of the framework provides some secondary benefits, such as exposure, addition to a curated library, etc., unless written into a legislation by any jurisdiction/regulatory body.
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the framework offers to them.*	• Policy makers • Developers • Health professionals • Researchers • Healthcare Institution • Vendors • Quality Reporting Agency • Regulatory Agencies • Certification Bodies The framework is based on the lifecycle of an app, as experienced by an individual consumer, from first deciding to download an app, to determining what happens with consumer data after the app has been deleted from a smartphone. It is important to note that the Framework does not speak directly to the specific health or clinical functionality of an app but can be

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<table>
<tr><td></td><td>extended to do so through the use of profiles (with constraints and/or extensions) developed on top of cMHAFF.

The AF (application framework) provides a path to assessments that can span a range including self-attestation, testing, endorsement, and/or certification (voluntary or regulatory); and promotes opportunity for certified apps to claim their conformance, and as a consequence, consumers who use the apps, and providers who recommend them, can be more confident of an app's rigor in enforcing basic security, its respect for the privacy of individuals, and the usefulness of data for improving and maintaining a better state of health.</td></tr>
<tr><td>Assessment Subject</td><td>Mobile health apps in general, medical apps, lifestyle and wellness apps,</td></tr>
<tr><td>Assessment Domain Coverage
Which assessment domains does the framework address specifically?
Does the framework consider, somewhat considers or does not consider the domains?</td><td>
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<tr><td>Validity</td><td></td><td></td><td>x</td></tr>
<tr><td>Interoperability</td><td>x</td><td></td><td></td></tr>
<tr><td>Technical stability</td><td></td><td>x</td><td></td></tr>
<tr><td>Effectiveness/Efficacy/Efficiency</td><td></td><td>x</td><td></td></tr>
<tr><td>Accessibility</td><td></td><td>x</td><td></td></tr>
<tr><td>Scalability</td><td></td><td></td><td>x</td></tr>
<tr><td>User experience and usability</td><td></td><td>x</td><td></td></tr>
<tr><td>Security</td><td></td><td>x</td><td></td></tr>
</table>
</td></tr>
<tr><td>Is there a clear process detailing how the assessment framework is to be applied? Please describe.</td><td>What roles are there?

App owner self-attestation, tester/inspector, 3rd party certifying body

What processes are defined?

cMHAFF labeling of App

How long does a typical assessment take?

2 – 4 hrs per role</td></tr>
</table>

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	What is the assessment outcome – qualitative, quantitative (e.g. score) and how is it to be interpreted? Assessment outcome is visualized by the *mLabel*. Process of assessment is described but definite scores have not been implemented yet.
Explain the framework's sustainability and business model.	The framework is targeted to be released as an HL7 normative standard. As per HL7 policy, all HL7 standards are freely available for use by anyone. The copyright remains with HL7. The HL7 Mobile Health Work Group developed the standards and maintains it.
Presentation and visualization of the assessment results	No available information

Framework Name	Continua Design Guidelines (CDG)
Short Description *What is the purpose of the framework? What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.*	Continua Design Guidelines is the only secure end-to-end ICT framework for ensuring the interoperability of personal connected health and care using open standards, to create a secure and interoperable health data exchange in personal connected health world-wide.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*Personal Connected Health Alliance* (PCHAlliance). USA https://www.pchalliance.org/
Owner Name	*Personal Connected Health Alliance* (PCHAlliance).

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The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.	
Owner Type	Non-governmental institution Not-for-profit
Year of Creation	2008
Website / Web Presence	https://www.pchalliance.org/continua-design-guidelines
Update Frequency *Is the framework revised and updated periodically? How often?*	Annual
Last Update	2019
Geographical Application Scope *Provide a type and name the actual geographical location(s).*	International: World-wide
Conformity Basis	Voluntary – the use of the framework provides some secondary benefits, such as exposure, addition to a curated library, etc.
Target Audience(s) and Value Propositions *List the main target audiences and elaborate the value the*	• Healthcare providers, inc public and private insurers to achieve outcomes at lower costs through outsourced population management services. • Remote care service providers (public and private) to integrate the information & communication technology (ICT) systems essential to realizing these lower costs. • Device and sensor companies the means to furnish the meaningful observations that enable these ICT systems to deliver vital signs

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framework offers to them.	data captured from multiple sources by people at home and on the move. • Pharmaceutical companies with the means to better measure drug efficacy The Continua Design Guidelines achieve interoperability between medical devices and services by providing a specific implementation of common international standards which are defined by recognized standards development organizations. They are built on four key principles: Unity: The best clinical minds united with the best technical minds to deliver and scale remote monitoring worldwide. Benevolent: The spirit of doing what we collectively believe is right for all persons is also freely and universally accessible. Inclusive: Inputs and improvements from any person are heard and considered. Holistic: We passionately work together to enable holistic understanding to make big data research possible.
Assessment Subject	Health apps in general, medical apps, lifestyle and wellness apps, guidelines
Assessment Domain Coverage *Which assessment domains does the framework address specifically?* *Does the framework consider, somewhat considers or does not consider the domains?*	

Domain	Considers >65% criteria "yes"	Somewhat considers The rest	Does not consider None criteria "yes" or "somewhat"
Privacy		x	
Transparency		x	
Safety		x	
Reliability		x	
Validity			x
Interoperability	x		
Technical stability		x	
Effectiveness/Efficacy/Efficiency		x	
Accessibility			x
Scalability		x	
User experience and usability			x
Security		x	

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Is there a clear process detailing how the assessment framework is to be applied? Please describe.	CDG provides a framework for use of standards to drive interoperability and assess for interoperability. That may overissues like privacy and security and usability, but only in so far as those are addressed by standards. Standards may provide connectivity, but it is the uniform implementation of these standards that is essential for interoperability. Going beyond the implementation guidance of the CDG, Continua also provides for product assurance by maintaining a compliance and interoperability assessment program. This includes all the tools, processes and procedures necessary to demonstrate product conformance to required standards crucial for interoperability.
How is the assessment performed?	The Conformity Assessment Scheme (CAS) by *Continua* achieves that delicate balance between a comprehensive and rigorous method for ensuring devices meet stated functional requirements yet demonstrated in an affordable time and cost that allows vendors to be profitable in a highly competitive market. It provides a transparent and universal mechanism to assure compliance with procurement requirements. This is especially valuable in the complex, demanding and highly fragmented healthcare IT market. CAS by Continua defines high value objective methods and criteria for 3rd party certification of test results that are recognized worldwide.
Explain the framework's sustainability and business model.	Development of the CDG is through the benevolent participants of PCHA. The assessment framework is developed and maintained through membership fees which fund a dedicated 3rd party to review the CDG for testable items, develop test procedures, write test scripts to allow automated consistent testing, and validation. Vendors seeking certification pay a nominal fee to PCHA.
Presentation and visualization of the assessment results	Products that have successfully achieved 3rd party certification are listed in the PCHA Certified Products Showcase. Products that have self-declared compliance to the CDG may be posted in the Compliant Product Listing.

Framework Name	EU guidelines on assessment of the reliability of mobile health applications
Short Description *What is the purpose of the framework?*	The purpose of the mHealth app assessment guidelines is to establish a framework of safety, quality, reliability and effectiveness criteria to improve the use, development, recommendation and evaluation of

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What does it assess? What is the scale (geographical coverage, assessed assets, link to policy), etc.	mHealth apps and to facilitate prevention and an overall healthcare advancement through a controlled use of mobile technology.
Creator *The entity or group of entities which created the framework. Legal name, website, country and other details.*	*CONSARD Limited* for European Commission http://www.consard.co.uk
Owner Name *The entity responsible for implementing the framework, maintaining and updating it. May be the same entity as the creator.*	European Commission
Year of Creation	2016
Website / Web Presence	https://ec.europa.eu/digital-single-market/en/news/report-working-group-mhealth-assessment-guidelines
Update Frequency *Is the framework revised and updated periodically? How often?*	No available information
Last Update	2017
Geographical Application Scope *Provide a type and name the*	International: EU countries

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<table>
<tr><td>actual geographical location(s).</td><td></td></tr>
<tr><td>Conformity Basis</td><td>Voluntary – the use of the framework provides some secondary benefits, such as exposure, addition to a curated library, etc.</td></tr>
<tr><td>Target Audience(s) and Value Propositions
List the main target audiences and elaborate the value the framework offers to them.</td><td>

Developers
Health professionals
Researchers
Citizen
Health System

These guidelines build on existing initiatives and best practices from across Europe and beyond. They propose a set of common quality criteria and assessment methodologies to help different stakeholders including end users, developers, payers of care, and vendors of electronic health record systems to assess the validity and reliability of mHealth apps. This means that patients would be able to give health professionals access to data collected by the apps for the purpose of improved consultations.

These guidelines therefore address all other mHealth apps that are not for Europe medical devices, including apps that are used in a health and social care context which according to the intended use identified by the manufacturer do not fall under the definition of a medical device, as well as health & wellbeing apps aimed primarily at disease prevention.

For those mHealth apps that are regulated by existing EU legislation as medical devices, the guidelines propose some additional voluntary assessment criteria. They cover the so-called ‘grey zone’ of those apps that just fall below the lowest category of medical devices (Class 1), through to apps such as medical appointment booking apps that nevertheless involve exchange of potentially sensitive personal information</td></tr>
<tr><td>Assessment Subject</td><td>Health apps in general, medical apps, lifestyle and wellness apps, Health services</td></tr>
<tr><td>Assessment Domain Coverage
Which assessment domains does the framework address specifically?
Does the framework</td><td>
<table>
<tr><th>Domain</th><th>Considers
>65% criteria “yes”</th><th>Somewhat considers
The rest</th><th>Does not consider
None criteria “yes” or “somewhat”</th></tr>
<tr><td>Privacy</td><td>x</td><td></td><td></td></tr>
<tr><td>Transparency</td><td>x</td><td></td><td></td></tr>
<tr><td>Safety</td><td></td><td>x</td><td></td></tr>
</table>
</td></tr>
</table>

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consider, somewhat considers or does not consider the domains?	Reliability		x	
	Validity	x		
	Interoperability	x		
	Technical stability		x	
	Effectiveness/Efficacy/Efficiency		x	
	Accessibility		x	
	Scalability			x
	User experience and usability		x	
	Security		x	

Is there a clear process detailing how the assessment framework is to be applied? Please describe.

A total of nine criteria/domains, as all contributing to the data quality objective, have been identified based on the analysis of existing AF that are relevant for the assessment of mHealth apps:

- Reliability
- Desirability
- Credibility
- Safety
- Security
- Transparency
- Usability
- Effectiveness
- Stability

In order to use the guidelines to produce an assessment of the app, it is evaluated against the scrutiny questions for each domain. This involves a combination of a scoring system and of mandatory pass/fail questions; apps failing a mandatory question or not reaching a sufficiently high score are not recommended.

What processes are defined?

- Initial validation – that the app exists, is appropriate for the evaluation, is downloadable etc.
- Risk assessment – which in turn determines the appropriate level of scrutiny
- Scrutiny – of both the technological and the medical aspects.
- Scrutiny forms a combination of a scoring system and mandatory pass/fail questions; apps failing a mandatory question or not reaching a sufficiently high score are not recommended.

What is the assessment outcome – qualitative, quantitative (e.g. score) and how is it to be interpreted?

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	A risk-related score for each app, with a cut-off below which the app is rejected, plus some questions for any of which the answer 'no' means rejection. Against each question there is then an indicator of mandatory, desirable, additional, or not applicable. Confirming the answer yes to a question then either keeps the app in play if the indicator is mandatory (no would result in rejection), or scores 6 for desirable or an extra 4 (making 10 in total) for additional. A no to any desirable or additional question scores zero, as also does any answer where the risk level indicates not applicable. The total score for each section is then divided by the number of scored questions to give an overall score. Scores below a set level result in rejection of the app. There are endless versions of this possible. One option to consider is giving higher weighting for some questions & lower weighting for others.
Explain the framework's sustainability and business model.	The development of the guideline was supported by the European Union.
Presentation and visualization of the assessment results	No available information

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Annex 4. Results visualization: criteria coverage within each domain by the analysed frameworks

The Hub research team has made a significant effort to develop attractive and informative pieces of visual information (visualizations) based on the results about evaluation domains and criteria for health apps.

Specifically, it has been visually represented to what extent the criteria under each of the 12 domains are covered in the 24 frameworks analysed. The longer a segment is, more frameworks have considered it (Table 13).

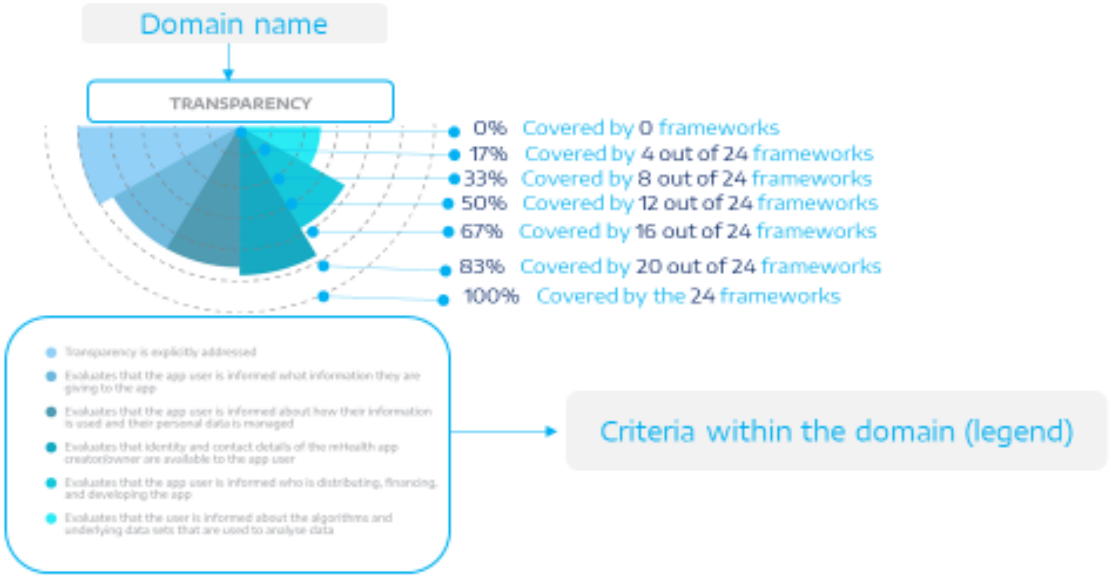

Table 13. Example of visualization and interpretation

The following tables present the visualization for each domain and their criteria.

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Table 14. Visualization 00 – General (12 domains and their criteria)

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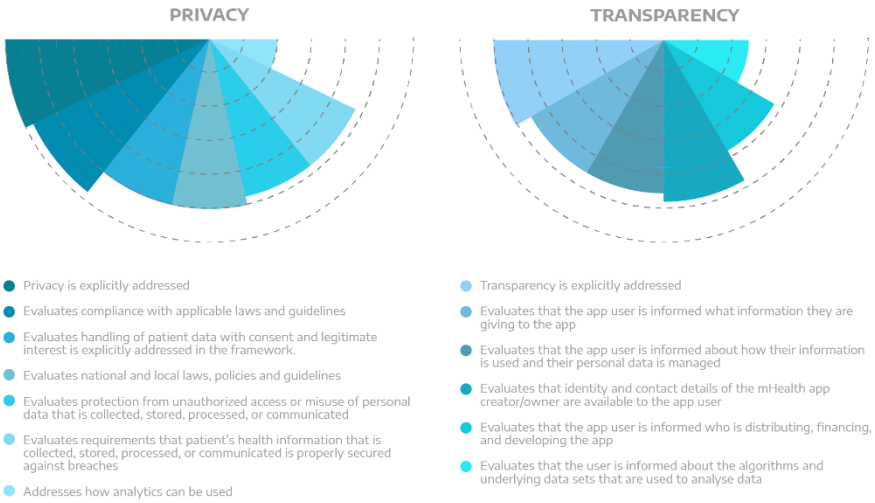

Table 15. Visualization 01 – Privacy and Transparency

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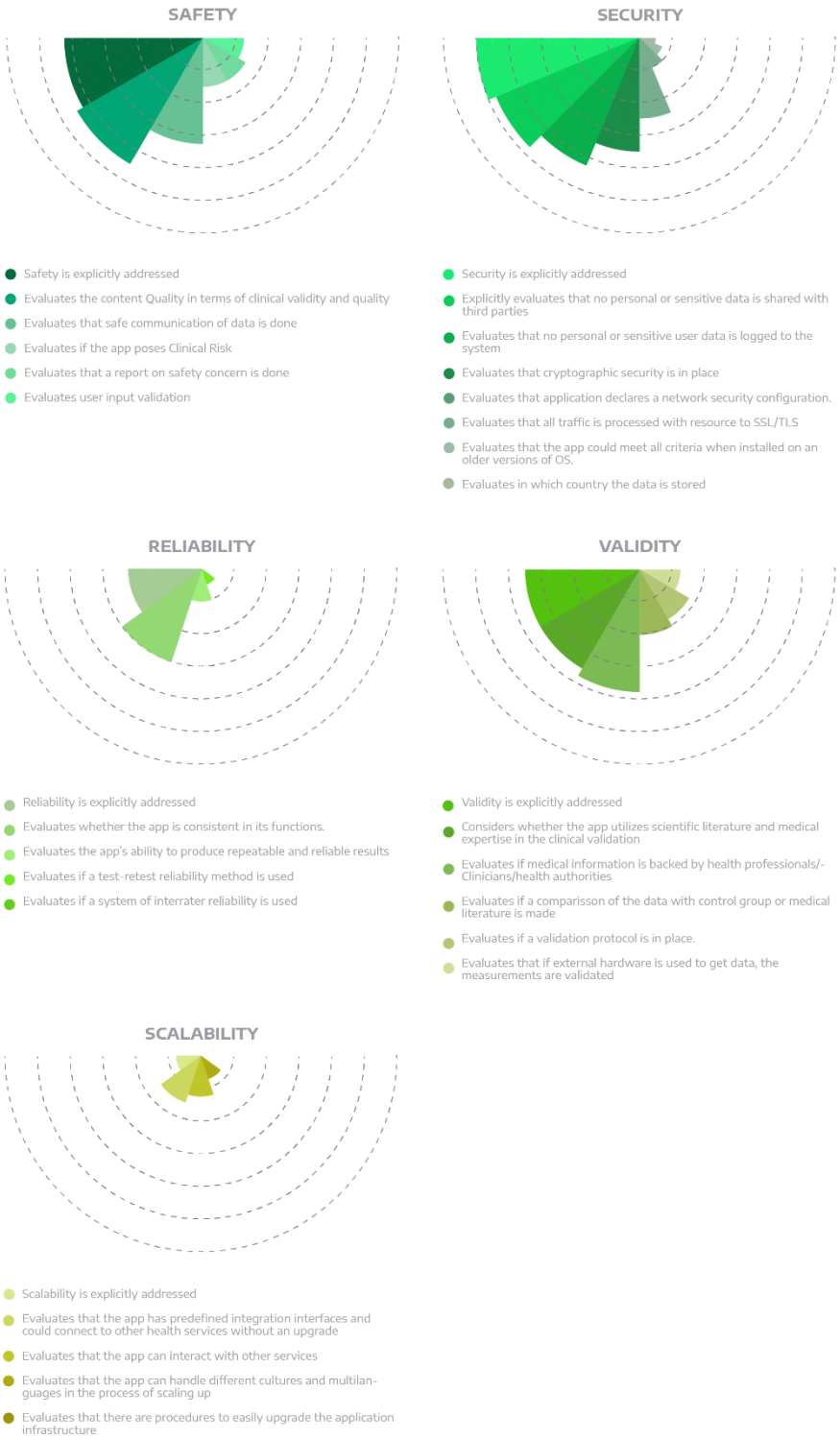

Table 16. Visualization 02 – Safety, Security, Reliability, Validity, Scalability.

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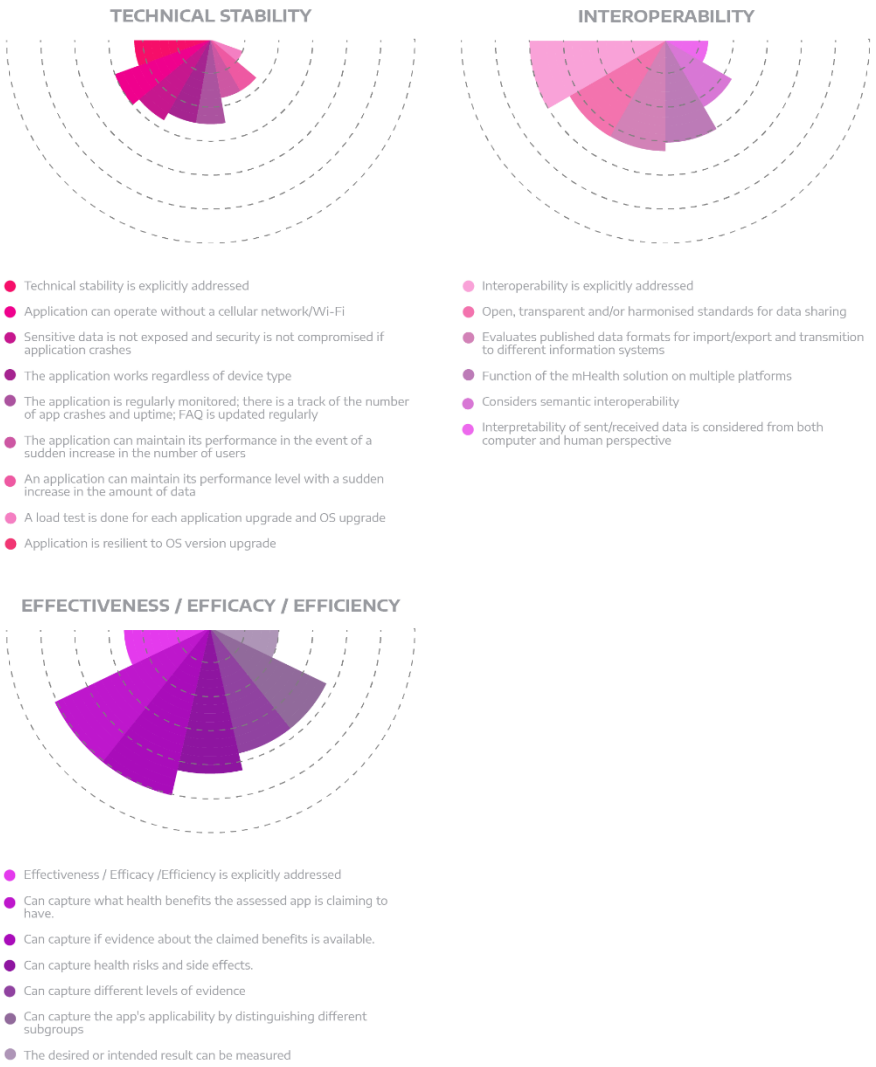

Table 17. Visualization 03 – Technical stability, Interoperability, Effectiveness

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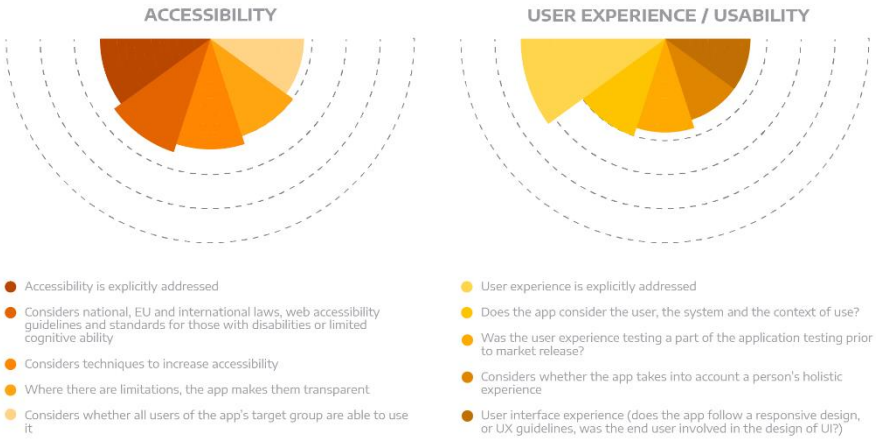

Table 18. Visualization 04 – Accessibility, User experience/Usability

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Annex 5. Comments received to the Hub orientations document through open consultation

On June 2021, the European mHealth Hub opened a consultation period for the new content developed.

On one hand, two new aspects were suggested under security domain for the piece "Aspects in which health apps assessment frameworks could be enriched" (see aspects 26 and 27)

On the other hand, the document 'Hub orientations when setting up a health apps assessment framework and evaluation process' received several comments, that were taken in consideration where appropriate or feasible, and that are presented here for those who want to consult it.

- Depending on the *intended use of an app*, it should meet adequate requirements related to safety and performance, efficacy and then provide proofs related to the benefits that the app is deemed to bring. Certain requirements apply to all cases, such as security and privacy related, but others apply adequately depending also on the *classification of the app*, e.g.: just for informative purpose, well-being, improvement of effectiveness and quality of some processes, medical device supporting clinical decision process, public health interest, candidate app for reimbursement.
- All apps that can contribute to improvement of certain health related parameters and can be scaled up to other regions/counties. An app that may have a purely voluntary position in one country may get funding or even reimbursements in another country. A suitable policy should be applied to (non)inclusion of apps that apparently do not meet all requirements, especially if no proof of the benefits is provided.
- Certain institutionalization of the assessment process is a legitimate question. The AF is quite complex and requires specific expertise to be systematically available for practically all the stakeholders. If not standalone institution(s) are envisaged (which might be an option), some existing ones may be considered. e.g, EMA (which provides support to medicines developers and evaluates clinical trial data) or an institution involved in CE marking and ISO 13485 certification.
- Though a voluntary approach to assessment of mHealth apps seems to be realistic, suitable EU legislation may be necessary to clarify the role the assessment position of it in digital health development in EU countries. This appears necessary if the assessment process shall be sustainable and its results should have a value for the applicants. A kind of inspiration might be found in the currently (6.2021) finalized EU Digital Governance Act, which, among others, adjusts the position of certain institutions acting in EU Member States in an effectively voluntary environment.
- The 12 assessment domains seem to be adequate though their presentation is not very clear from a future framework point of view (it is a report of what all was reviewed). Clinical benefits, e.g., are distributed in the Effectiveness and Validity domains and assessment of health-related benefits incl. Evidence-Based Medicine approach is not

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very clearly presented though the assessment process in this doc often references reimbursement ambition. So, the criteria should be rewritten so that they are comprehensive.

- Ethical requirements may have a better position, but if they are presented in a selected domain, they should be more visible, e.g., by renaming domain Effectiveness to "Effectiveness and ethical".
- Then, the requirements seem to be only app-oriented but their provision and operation by a concrete company is not adequately addressed; some apps may need technical support and even established systems for training of users. One domain (Technical stability) may therefore also comprise technical support.
- Changes are proposed above. Apps that have higher ambition in supporting the health status of their users may require adequate proof of what they declare so that there is credible information available for authorities and professionals regarding possible inclusion of the apps into health services. Obtaining such a proof may be part of the assessment process or the process includes just evaluation of available information, e.g., results of clinical studies with patients performed separately.
- Maintenance of AF relates to the answer provider to Q.3 above. Maintenance of AF is needed, as only experience with AF will show what can be improved. Moreover, due to development of digital technologies and their increasing proliferation into medical processes requires systematic operation, research or scientific support.
- One possible approach is outlined in the answer to Q.3. If the assessment of apps has a clear value for applicants (which may be both companies and regions seeking suitable apps), costs associated with the processes may be passed to the applicants as known in other cases. The value should consist especially in reduction of barriers that an applicant with an app may face in country X so that the processes that are similar and already performed are not repeated again, based on provisions in a new legislation initiative dealing with digital apps in EU. This shall however allow to maintain decision power to local authorities, e.g., in case of reimbursement, as this remains a national issue.
- This is also associated with answers to Q.3 and Q.7. Dedicated part of EU legislation may lay down pertinent requirements.
- The above outlined approach (described esp. in Q.3, Q7. and Q8) will probably require debates with a number of stakeholders in the EU, so it is advisable to start as soon as possible after the selected approach(es) is accepted eg. by EC.
- The lack of interest may be influenced by the current relatively small portion of the business in healthcare represented by mHealth apps. Natural development is not useful to speed up external interventions. Advent of apps with significant economic or medical benefits may change it. AI/ML may help in this. The barrier for collaboration is partially caused by the multidisciplinary nature of mHealth, and could be gradually overcome particularly by demonstration of the benefits of the new apps for all the currently separated stakeholders.
- A conclusion from D2.1 was that security and privacy were only 'somewhat considered' and it varied AF to AF. The capability exists 'now' to have the security and privacy of

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mApps assessed to stringent standards using automated vulnerability scanning. The scanning and analysis, includes static, dynamic, behavioural and forced path execution. Results can be provided that will inform the assessor / developer, what vulnerabilities there are in the app, where they are (line of code), why they are important and advise on remediation. mApp assessment, can be a lengthy process, if the framework includes automated vulnerability scanning, it can streamline and enhance the security and privacy aspects of the assessment process, (e.g., *Kryptowire* has a unique, automated, closed loop solution that provides results as above in less than 2 hours, average 30mins), thereby enabling more focus on other aspects, e.g. health merits.... The richness of the information means that mApps will improve over time.

- It would be worthwhile to consider which domains are not (strongly) regulated and how their inclusion may drive or stimulate better uptake, for instance in interoperability.
- Continual Assessment of mobile apps should also be considered. mApps have multiple updates dependent on the complexity of the mApp. Update frequency ranges from several times a year to every fortnight for example. These updates may introduce vulnerabilities into the mApp. In addition, with mApps, external factors also push for continual assessment. Mobile Phone operating systems may be updated, potentially introducing security and privacy issues and of course malicious players target health systems. Vulnerability databases are constantly being updated and a mApp developer and assessor need to be aware of these known vulnerabilities.
- I agree with it, this forms a challenge considering app assessment frameworks

Finally, the Learnings/selection of innovative insights and the commonalities and mutual recognition did not receive any written feedback.

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