HAUTE AUTORITÉ DE SANTÉ

MEASURING
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STANDARD

Update of the standard for the assessment of digital services in the mHealth sector

Validated by the HAS Board on 20 November 2024

Description of the publication

Title	Update of the standard for the assessment of digital services in the mHealth sector
Working method	The method used is based on a systematic review of the literature, interviews with stakeholders, comparisons of criteria relative to medical content quality and submission of the document to a review group.
Objective(s)	To identify the points of convergence and divergence between the criteria relative to medical content quality in the 2021 HAS standard and the ISO 82304-2 standard via a gap analysis. To propose, if necessary, an updated standard relative to quality criteria for the medical content of apps in the health sector.
Targets concerned	Health system users Healthcare professionals *"Mon espace santé"* referencing committee and services responsible for examining requests All public or private stakeholders proposing services aimed at users in the areas of health, wellness and autonomy Software and mobile app developers
Requester	Ministerial Delegation for Digital Health (DNS)
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Literature search	Marina RENNESSON; Laurence FRIGERE
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General synopsis

Background

"Mon espace santé" [My online health space] (MES) is a platform developed by the Ministerial Delegation for Digital Health (DNS) and the French National Health Insurance Fund for Salaried Workers (CNAM), which includes a catalogue of referenced digital health services aimed at users. With a view to this referencing, the HAS had been consulted in July 2020 and had published a standard relative to medical content quality criteria applicable to the mobile health (mHealth) sector. Since then, the ISO 82304-2 standard has been published, divided into five headings: product information, healthy and safe, easy to use, secure data and robust build. Consequently, this standard targets quality criteria that are at least partly of the same order as the current criteria for referencing in the *"Mon espace santé"* platform.

In this context, the DNS consulted the HAS for an "Update and extension of the standard for the assessment of apps in the digital health solutions mobile health (mHealth) sector". Hence, on 19 December 2023, the HAS published the project scoping document, implemented following this referral and aimed at presenting its objectives, the intended scope and the scheduled procedure.

Challenges and objectives

This project aims to optimise the quality criteria for medical content, taking into account the existing standard, and also to optimise the referencing process.

The aim is to:

- identify the points of convergence and divergence between the criteria relative to medical content quality in the 2021 HAS standard and the ISO 82304-2 standard via a gap analysis;
- propose, if necessary, an updated standard relative to quality criteria for the medical content of apps in the health sector.

In addition, in the context of this work, the CNAM asked the HAS to broaden its proposals to include changes to the referencing criteria, enabling the committee to take into account the relevance of medical content, the organisational impact of solutions and their compliance with conventional rules.

Methodology

The method of production of this standard is based on:

- a **gap analysis** between the criteria of the 2021 HAS standard and ISO 82304-2;
- **interviews with stakeholders** (users and mHealth app developers);
- a **systematic review of the literature**;
- a **comparative synopsis** of the 2021 HAS standard with respect to the *"Mon espace santé"* (MES) criteria;
- submission of the document to a **review group**.

Comparison of the 2021 HAS standard criteria with ISO 82304-2

ISO 82304-2 is an experimental standard and its ongoing examination by the ISO committee will determine whether it is renewed or withdrawn. The comparison demonstrated that 11 criteria from the 2021 HAS standard are considered to be convergent with ISO 82304-2 criteria but that some

notions in the 2021 HAS standard are not present in their entirety. Therefore, the ISO standard does not cover all the current medical content quality criteria for referencing in MES.

Discussions with stakeholders

Use of the catalogue of MES services by patients or health system users remains limited. This use may develop with the referencing of a larger number of apps, in particular with solutions that can be synchronised with the shared medical record part (DMP) of MES for data sharing.

User representatives indicated that the information available on the digital services referenced in the catalogue is limited and that improvements could be made to better inform users' choices.

ISO 82304-2 appears to be little known in the ecosystem and its use by manufacturers is very limited.

Analysis of the literature and assessment practices

Analysis of the literature shows that there is currently no consensus with respect to the quality of medical content and standardised methods to assess mHealth apps. Nevertheless, some tools have been validated and are being used as a basis for the development of more customised tools. That is the case with the MARS and Enlight Suite scales, for example, these being the most frequently used scales to assess apps.

There have also been developments in the methods used to assess mHealth apps with a view to their referencing or certification/labelling, with projects aimed, in particular, at international collaboration. Some organisations have put in place this type of assessment to demonstrate the reliability of digital solutions and thereby boost public confidence in their use.

The scopes of the digital services targeted and the assessment dimensions are very heterogeneous. Three main assessment models are observed: a self-declaration model, a model based on the assessment of simple criteria by a public or private body, and a model based on the assessment of numerous criteria depending on the complexity of the digital solutions.

Several international agencies have already compared ISO 82304-2 with their own assessment protocols with a view to referencing. These agencies concluded that their own assessment processes were more stringent than the ISO standard.

Finally, the review of international assessment practices did not identify any processes that included an assessment of the interest of applications separate from an assessment with a view to funding.

Conclusion

Given this information concerning ISO 82304-2, it does not appear to be necessary to replace the criteria relating to medical content quality for referencing in MES. Nevertheless, and in accordance with the referral, the work to update the HAS standard took into account the formulation of the ISO standard criteria, where these converged with the 2021 HAS standard.

Finally, five MES referencing criteria relative to medical content quality have been updated and two new criteria have been added.

Outlook

With a view to offering a greater number of referenced services to users, while at the same time guaranteeing their quality, proposals for the referencing process and the catalogue of services have been formulated. In addition, the HAS recommends identifying the criteria relating to the quality of medical content in a dedicated section, separate from the ethics section.

1. Introduction

1.1. Source of the request

The Ministerial Delegation for Digital Health (DNS) consulted the French National Authority for Health (HAS) for an *"update and extension of the standard for the assessment of apps in the digital health solutions mobile health (mHealth) sector".*

1.1.1. Presentation of the *Mon espace santé* digital service catalogue

Digital health is a fast-growing sector that represents a genuine opportunity to improve and optimise the care of users. Thousands of apps in the field of health and wellness are currently available on download platforms, making it difficult for users to choose health apps.

In this context, a catalogue of referenced digital services has been developed on the *"Mon espace santé"* (MES) platform on the initiative of the DNS and the French National Health Insurance fund for salaried workers (CNAM).[1] These digital services, developed by public or private players, are aimed at users, patients and their carers in the fields of health, wellness and maintenance of autonomy. They may be apps, software, websites or any other solution related to a smart object, with or without medical device status. The digital services referenced may include a feature for exchange of data or read and/or write documents with MES, subject to user consent.[2]

Referencing of a digital service in the MES service catalogue requires that it comply with referencing criteria that aim to guarantee its quality to users; it is not an assessment of its clinical or organisational value.

1.1.2. *"Mon espace santé"* referencing procedure

Article L. 1111-13-1 of the French Public Health Code stipulates that "In order to be referenced and integrated into the digital health space, the digital services [...] must comply with the interoperability and security guidelines drawn up by the group mentioned in article L. 1111-24, the ethical commitment guidelines and the labels and standards imposed in the digital health space mentioned in article L. 1111-13-2. […]". Hence, each digital service that is a candidate for referencing must comply with the digital health policy, which is published every year and sets out the common rules on security, inter-operability and ethics that apply to digital health services.[3]

The criteria applicable to referencing were defined by order of 8 September 2022[4] and updated in October 2023.[5] The referencing procedure is initiated at the request of the manufacturer and involves DNS assessors and a referencing committee jointly chaired by the DNS and the CNAM. First of all, the assessors will check that the apps comply with these criteria and will send an assessment report to the committee, which will issue a favourable or unfavourable opinion for referencing.

[1] L'Assurance Maladie, Le catalogue de service de Mon Espace Santé [National health insurance system, the *"Mon Espace Santé"* service catalogue]
[2] G_NIUS, Je vérifie si mon service numérique est concerné [Check whether my digital service is concerned]
[3] ANS, La doctrine du numérique en santé [Digital health policy], 2023 version
[4] Order of 8 September 2022 relative to the criteria applicable to referencing of digital services and tools in the service catalogue of the digital health space
[5] Order of 23 October 2023, amending the order of 23 June relative to the criteria applicable to referencing of digital services and tools in the service catalogue of the digital health space

After the referencing committee has issued its opinion, the Ministry of Health makes the decision with respect to referencing. In the event of a positive decision, referencing is currently valid for a period of one year. The developer must submit a request for renewal of referencing before the end of the first year. If the renewal is accepted, the digital service is then referenced for a further period of 2 years. At the end of the initial one-year period and the two-year renewal period, the developer must submit a new request for referencing. Furthermore, in the event of a substantial modification to the referenced service, the developer must submit a new request for referencing. The digital service may also be reassessed if a third party or competent authority reports a breach of the referencing requirements or as part of continuous assessment of the service's compliance.[6]

The criteria used for referencing are organised into four categories: **urbanisation**, **interoperability**, **security** and **ethics.**

1.1.3. Development of criteria relative to medical content quality

In July 2020, with a view to this referencing, the HAS had been consulted by the DNS to draw up a list of medical content quality criteria used in the mHealth sector. The HAS therefore published a standard[7] in 2021 designed to recommend a set of medical content quality criteria to ensure a sufficient level of quality of apps in the context of referencing of health apps in the MES.

Following the publication of this standard, five criteria relating to the quality of medical content were included in the ethics section for MES referencing criteria. The MES referencing criteria relative to medical content quality and the criteria from the 2021 HAS standard were compared in table 1 below.

Table 1: Comparison of MES criteria for the quality of content section versus the 2021 HAS standard

MES referencing criteria for the quality of content section	Corresponding 2021 HAS standard criteria
QUA.1.1: The system must mention and document that the expertise of the persons selecting, validating or writing the medical/health content published in the service is appropriate to the topic covered by the service. This information, along with the conflicts of interests of persons, is available to users of the digital service and easily accessible to all. When medical content is taken directly from the website of an organisation, in particular a national agency or a learned society, for which the information is reputed to be reliable, the name of the organisation and the URL of the website must be indicated.	C01: Presence of an organisation or an editorial expert committee selecting and validating the information published in the app.
	C02: Experts (healthcare professionals, engineers, algorithm experts, professional bodies, patient or consumer associations, etc.) are involved in producing the content available in the app.
	C03: Declarations of conflicts of interest of the different contributors are available to view for all.

[6] *"Mon espace santé"* referencing guide, version 3.8

[7] Assessment of apps in the mobile health (mHealth) field, HAS, 2021

QUA.1.2: The system must enable the key sources and scientific references used to develop the medical/health content of the service to be consulted by all.	C04: Key sources and references for publications justifying app content are documented and are available to view by all.
QUA.1.3: The system must document that the process for monitoring and updating the sources and scientific references used to develop the medical/health content of the service is appropriate to the topic covered by the service. This information is available to users of the digital service and easily accessible to all.	C05: The process for monitoring and updating key sources and references in relation to publications is documented.
QUA.1.4: If the solution has undergone clinical assessment and levels of evidence have been produced, this information is available to users of the digital service and easily accessible to all.	C06: Where a specific assessment of the product and levels of evidence is available, these suitable references are available to view by all.
QUA.1.5: If the service requires interpretation of content for health purposes (health data, scientific content, etc.), the system must guarantee that this is carried out by healthcare professionals with expertise appropriate to the topic covered by the service or by specifically trained competent persons.	C09: In the case of human (non-automated) interpretation of content for health purposes (health data, scientific content, etc.), this is carried out by suitable healthcare professionals for the topic studied or specifically trained competent persons.

Some criteria relative to medical quality content present in the 2021 HAS standard have not been used in the current criteria for MES references. These are criteria C11 and C12 relating to user involvement and description of the end-use, indicated in table 2 below.

Table 2: HAS standard medical content quality criteria not used in the MES criteria

MES referencing criteria for the quality of content section	Corresponding 2021 HAS standard criteria
Criterion not used	C11: The main users are involved in the different app development phases.
Criterion not used	C12: The main end-use (objective or purpose) of the product is the subject of a precise description available to view by all.

Finally, the other criteria proposed by the HAS in 2021, which overlap with the ethical criteria prepared by the DNS, have been incorporated in the “accessibility”, “ethics and transparency” and “artificial intelligence” sections.

The MES referencing criteria were finalised before the publication of an international standard relative to the quality and reliability of health and wellness apps in 2021.[8] This ISO 82304-2 standard covers five main headings:

- product information;
- healthy and safe;
- easy to use;
- secure data;
- robust build.

Consequently, this standard sets out quality criteria that apply to all the fields targeted by the current MES referencing criteria. The DNS therefore consulted the HAS in 2022, following on from the 2020

[8] ISO/TS 82304-2:2021 “Health software – Part 2: Health and wellness apps – Quality and reliability”

referral, to assess the scientific relevance of aligning the medical content quality criteria for MES referencing with the criteria in this ISO standard and, if applicable, with the current MES referencing criteria relative to medical content quality.

1.2. Challenges

The objective of this work is to optimise the criteria relative to medical content quality and, if applicable, update them in the light of ISO 82304-2. It also aims to optimise the process for referencing of apps in the MES service catalogue. Hence the challenge of this referral is to guarantee the medical content quality of the apps referenced and develop user confidence in order to contribute to the informed use of the apps available on MES.

In addition, the CNAM asked the HAS to broaden its proposals to include changes to the referencing criteria, enabling the referencing committee to take into account the relevance of the medical content of solutions, their organisational impact and their compliance with conventional rules.

1.3. Objectives and scope

The objectives of this work are to:

- identify the points of convergence and divergence between the ISO 82304-2 standard and the medical content quality criteria of the 2021 HAS standard, on which the MES referencing criteria are based, via a gap analysis;
- propose, if applicable, an updated standard for MES referencing criteria relating to medical content quality.

The scope of this work concerns all digital services that may be referenced in the MES service catalogue.

1.4. Working method

The method for the development of this document is based on:

- a **gap analysis** comparing ISO 82304-2 with the medical content quality criteria of the 2021 HAS standard, on which the MES referencing criteria are based;
- **interviews with stakeholders** (users and mHealth app developers);
- a **systematic review of the literature**;
- a **comparative synopsis** of the 2021 HAS standard with respect to the *"Mon espace santé"* (MES) criteria;
- submission of the document to a **review group**.

The methodologies implemented for each component of the project will be developed in this document.

1.5. Regulatory information

This updated standard does not replace the legislative and regulatory framework in force, particularly relating to medical devices, artificial intelligence (AI), personal data protection and health data. The application of the criteria set out in this standard is intended without prejudice to the regulations in force.

The HAS would like to point out that the CE mark is mandatory for digital services with medical device status. In addition, the European regulation on AI[9] published on 12 July 2024, will be phased in progressively concerning apps considered to be AI systems with a high risk.

Finally, this updated HAS standard does not constitute an assessment tool for inclusion in lists qualifying for funding.

[9] Regulation EU 2024/1689 of 13 June 2024 laying down harmonised rules on artificial intelligence

2. Comparison of the 2021 HAS standard criteria with ISO 82304-2

2.1. Background

The ISO 82304-2 standard relative to the quality and reliability of health and wellness apps was published in 2021, after the HAS standard was published online. It includes 81 criteria developed using the Delphi method, involving 83 experts, including industry and healthcare representatives. (1) The objective of the authors is to create a framework applicable on a global scale to assess the quality of health apps.

This standard has technical specification status, which means it must be examined at the latest three years after its publication.[10] The aim of this procedure is to re-examine the situation that led to the publication of the standard in order to adopt the technical specification in the form of an international standard or to withdraw the document. At the time of writing of this HAS standard, the decision whether to renew or withdraw the ISO standard is in the process of being examined.[11]

An expert review published in The Lancet Digital Health in 2022 reports that ISO 82304-2 could help improve the quality of health apps, but highlights its limitations given that it focuses on the design process rather than the evaluation of user outcomes. (2) According to the authors, in particular, the standard should require testing of solutions in representative samples of the users concerned by the app. Finally, the publication underlines that the standard would not prevent cases of misuse of the apps.

2.2. Methodology

A gap analysis was conducted to compare the criteria of the 2021 HAS standard with ISO 82304-2.

For this purpose, a convergence measurement based on four values was used:

- convergent, the given criterion is found in its entirety in the ISO standard;
- complementary, the given criterion is partially convergent with the ISO standard, but some of the notions of the criterion are not present in the ISO standard;
- nonconvergent, the given criterion is not found in the ISO standard;
- divergent, the given criterion presents requirements that contradict with the ISO standard.

2.3. Results

The HAS standard published in 2021 included 17 criteria detailed in annexe 1. Six of these were considered to be complementary and 11 convergent using the above convergence measurement. No criteria were considered to be nonconvergent or divergent. Figure 1 below illustrates this distribution, indicating the number of criteria concerned and the corresponding percentage in each category.

[10] ISO - Directives and policies

[11] ISO/TS 82304-2:2021 - Health software — Part 2: Health and wellness apps — Quality and reliability [consulted on 19 September 2024]

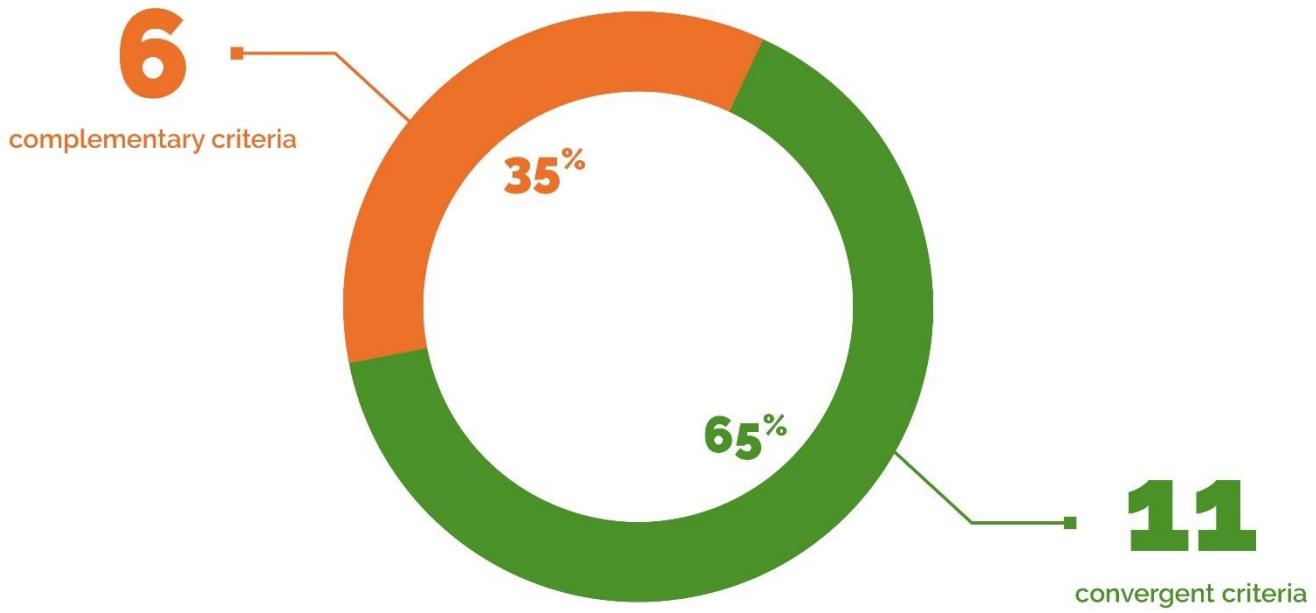

Figure 1: Comparison of the 2021 HAS standard criteria with ISO 82304-2.

Details of the criteria considered to be complementary or convergent with the ISO standard are summarised in table 3 below.

Table 3: Comparison of the 2021 HAS standard criteria with ISO 82304-2

	Topics of the criteria in the 2021 HAS standard	Notions absent from the ISO standard
Convergent HAS criteria (11) found in their entirety in the ISO standard	Sources and bibliographic references represented (C04, C05)	
	Level of evidence (C06)	
	Measurement quality in context of use (C07)	
	User support (C08)	
	Involvement of users (C11)	
	Description of objectives and contraindications (C12, C13)	
	Understandability and readability of the content (C14, C16)	
	User help (C15)	
Complementary HAS criteria (6) found partially in the ISO standard	Quality of the persons involved in the production of the content (C01, C02, C03)	It is not specified whether the experts contributing to the development of the apps are responsible for the selection and production of the medical content. In addition, declarations of conflicts of interest by the contributors are not required.
	Human interpretation of content for health purposes (C09)	The elements to be produced are not found: “when and how interpretation is implemented”.

	Automated interpretation of health content represented (C10)	The user is not informed whether or not artificial intelligence is integrated. In addition, the notion of studies evaluating algorithm performance is not explicitly found.
	Error prevention and understanding of information (C17)	The notion of redirection to a healthcare professional is not covered.

As regards the quality of the medical content, ISO 82304-2 does not provide any additional aspects compared to the criteria of the 2021 HAS standard. On the contrary, the ISO standard is less strict in terms of medical content quality, since it does not integrate in their entirety six of the criteria in the HAS standard. In conclusion, in the area of medical content quality, an app compliant with this ISO standard would not guarantee compliance with all the criteria recommended by the HAS in 2021.

In summary

ISO 82304-2 is an experimental standard and its ongoing examination by the ISO committee will determine whether it is renewed or withdrawn. The comparison demonstrated that 11 criteria from the 2021 HAS standard are considered to be convergent with ISO 82304-2 criteria but that some notions in the 2021 HAS standard are not present in their entirety. Therefore the ISO standard does not cover all the current medical content quality criteria for referencing in MES.

3. Discussions with stakeholders

3.1. Methodology

3.1.1. Stakeholders consulted

In the context of updating of MES referencing criteria, the HAS consulted representatives from mHealth app developers and user associations, as well as a member of the MES referencing committee:

- Mobile health app developer representatives:
  - France Biotech;
  - Numeum;
  - Snitem.
- User associations:
  - Endomind;
  - *Fédération Française des Diabétiques* [French Diabetics Association]
  - *France Assos Santé;*
  - *Union nationale de familles et amis de personnes malades et/ou handicapées psychiques* [French national union of families and friends of patients with mental illnesses or disabilities] (UNAFAM).
- MES referencing committee representative.

3.1.2. Consultation methods

Industry representatives were questioned about the strategies of developers to ensure the quality of the medical content of their apps and about their knowledge and use of ISO 82304-2. Their observations and comments concerning the MES referencing criteria relative to medical content quality were also collected.

In parallel, meetings were held with user associations to identify their needs and expectations when they are seeking a health and wellness app, and to exchange useful information that could be displayed in the MES service catalogue to help users choose an app.

The discussion with the user representative on the MES referencing committee also provided an opportunity to gather feedback on the applicability of the medical content quality criteria for app referencing and on the assessment methodology used by the referencing committee.

A summary of the exchanges is presented below.

3.2. Summary of stakeholder positions

3.2.1. Link between referencing requirements and regulatory requirements

The industry players consulted indicated that the low number of digital services referenced in the MES service catalogue (currently 32)[12] was related firstly to a lack of clarity in the requirements, considered to be excessively restrictive and opaque, and secondly to the cumbersome administrative nature of the referencing procedure. More specifically, they are surprised that the MES referencing requirements are the same irrespective of the type of digital service, whether it is a medical device or not. In fact, apps with medical device status must comply with the requirements of the European regulation on medical devices,[13] with some of these overlapping with the MES referencing requirements. This overlapping of criteria, concerning both criteria relating to content quality and other referencing criteria, has the effect of increasing the burden on manufacturers, who are obliged to put together two different dossiers, one for submission to the notified body responsible for CE marking and one for submission to the MES referencing committee. Hence, manufacturers highlight the need for a comparative analysis of the criteria in the standard already covered by CE marking obligations. According to the analysis conducted by manufacturers, only certain criteria that are partially covered should be examined for compliance with the referencing requirements when the app in question is a CE-marked medical device.

3.2.2. Use of the *"Mon espace santé"* service catalogue by users

Users were unanimous about the value of the MES service catalogue, which they see as a guarantee of trustworthiness when choosing an app and as a form of labelling. They also report that this service is currently little known to the general public, and the catalogue's usefulness is perceived as being limited due to the apps currently referenced, which do not yet allow data to be exchanged with MES and therefore with the shared medical record (DMP). However, user representatives have no reservations about the future acceleration in the use of MES once the service catalogue references apps that are interoperable with the MES DMP, which will enhance the MES features.

Discussions with user representatives also revealed that it was sometimes difficult for them to see the point of using certain apps referenced on MES. Although the purpose of referencing is not to assess the interest of apps but rather their quality in terms of ethics, security and interoperability, they suggested that improvements should be made to the information available to users in the MES service catalogue:

- addition of a rating system and user reviews;
- some apps are medical devices and, accordingly, may have been assessed by the HAS for funding purposes. A logo could be used to notify users that the *Commission Nationale d'Evaluation des Dispositifs Médicaux et Technologies de Santé*[14] (CNEDiMTS) has issued an opinion on the device, whether this opinion is favourable or unfavourable for funding. The users consulted pointed out that, in the event of a favourable opinion, it would be useful to indicate the conditions required to benefit from funding.

[12] On 19 August 2024

[13] European regulation 2017/745 on medical devices

[14] The CNEDiMTS is the HAS national committee for medical device and health technology assessment that examines all questions relating to the assessment of medical devices and health technologies with a view to their funding by the French national health insurance system, and to their proper use, including those funded in the context of hospital services.

Hence, user representatives agree that this type of arrangement would improve the content of the MES service catalogue and encourage users to use it.

3.2.3. Manufacturers' strategies for developing the medical content of apps

Manufacturers indicated that they implement strategies to ensure the quality of the medical content of their apps, based on writing by healthcare professionals and the use of recommendations. However, the user representatives consulted emphasised the lack of user involvement in the design and development of the content of apps.

Finally, it emerges from the exchanges that ISO 82304-2 is not currently used by manufacturers for the development of app content. This ISO standard appears to be little known in the ecosystem, probably because of its experimental nature and its limited lifespan of three years in the event of non-renewal. In view of the human and economic resources required to achieve compliance, the industry representatives consulted report that the take-up of this standard by manufacturers is limited compared with other regulatory requirements, in particular ISO 82304-1 relative to general requirements for product safety and IEC 62304, which defines the life cycle requirements for medical device software.

In summary

Use of the catalogue of MES services by patients or health system users remains limited. This use may develop with the referencing of a larger number of applications, in particular with solutions that can be synchronised with the shared medical record part (DMP) of MES for data sharing.

User representatives indicated that the information available on the digital services referenced in the catalogue is limited and that improvements could be made to better inform users' choices.

ISO 82304-2 appears to be little known in the ecosystem and its use by manufacturers is very limited.

4. Analysis of the literature and assessment practices

4.1. Reminder of the conclusions of the analysis of the literature in the 2021 HAS standard

The literature review carried out in the context of the first generation of content quality criteria led to listing of the functions performed by these apps, as well as their purposes, which include wellness, prevention, monitoring and treatment.

In 2021, the inventory showed a wide variety of assessment systems internationally, despite harmonisation initiatives. Although the assessment dimensions were the same overall, the level of precision of criteria and their distribution in the various categories differed. The assessment tools identified could be general or specific to certain apps. The criteria employed usually concerned scientific publication quality, i.e. source, author expertise, conflicts of interest, currency, levels of evidence. The assessment could be performed by the manufacturer in the form of a self-assessment or by a private or public organisation. The criteria used could depend on the proposed end-use of the app, the context of use and the target population. Finally, the results showed that when the app used or processed health data, the assessments became more complex and could involve assessment standards or guidelines with several hundred criteria. New initiatives were expected, in particular ISO 82304-2, the objective of which was to standardise assessment systems.

4.2. Updating methodology

The searches covered the period from January 2021 to March 2024 in order to identify scientific publications, in English and French, concerning assessment of app quality in the mHealth sector, before or after the work carried out by the HAS. The search concerned websites, technology assessments, recommendations and guidelines, consensus conferences, guides, meta-analyses, systematic reviews and clinical studies. The following sources were queried:

- the Medline database;
- the Cochrane Library;
- websites publishing guidelines;
- the websites of learned societies with expertise in the field studied.

The search strategy and the list of queried sources are detailed in annex 2.

This search was supplemented by the bibliographies of previous publications, the references cited in the documents analysed and the websites of agencies assessing apps in the mHealth sector.

The aim of the literature search is to update the results of the systematic literature review and the inventory of mobile health (mHealth) technology assessment systems set up internationally by public and private health agencies or decision-makers with a view to:

- updating MES referencing criteria relative to medical content quality;
- identifying new and updated tools for assessing mHealth apps;
- identifying new mobile app assessment methodologies.

4.3. Literature search results

4.3.1. Volumes

The literature search identified 678 bibliographic references, 23 of which were selected on the basis of their title and abstract.

The following references were not retained:

- those not incorporating quality assessment;
- those not specific to mHealth apps;
- those concerning a specific therapeutic field;
- those based on a customised tool developed to assess a given solution.

This process led to eight references being retained, mainly including systematic reviews and scoping reviews.[15] The selection process is illustrated in figure 2 below.

This search was supplemented by two references cited in the documents analysed.

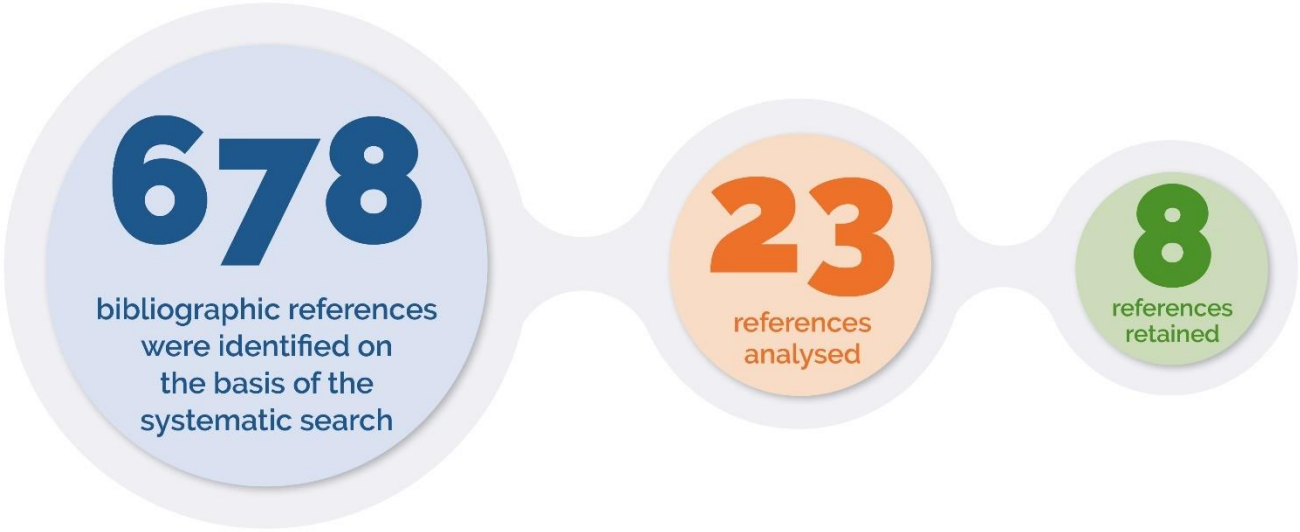

Figure 2: Article selection flow chart.

4.3.2. Key takeaways from the literature

The eight publications used in the literature review are described in table 4 below concerning their objectives and in annexe 3.

Table 4: Summary of the publications selected

Study	Objective
Azad-Khaneghah *et al.*, 2021	To review the rating scales used to evaluate the usability and quality of mHealth apps, and to compare their purpose, content, psychometric properties and intended target users.
Giebel *et al.*, 2024	To identify quality assessment tools for mHealth apps and determine relevant quality assessment dimensions.

[15] a "scoping review" is a type of knowledge synthesis that uses a systematic and iterative approach to identify and summarise a set of existing or emerging documents on a given subject (Zachary et al., 2018).

Grau-Corral *et al.*, 2021	To develop an instrument to assess mobile apps used in the healthcare context aimed at healthcare professionals and medical personnel (ISYScore-Pro score).
Henscher *et al.*, 2021	To analyse the different publications evaluating the criteria used to assess mHealth apps, as well as the scoring and evaluation methods used in this context.
Muro-Culebras *et al.*, 2021	To analyse the quality of the tools that are used to measure the quality of mHealth apps following the COSMIN[16] guideline.
Ribaut *et al.*, 2024	First phase of an overall project aimed at developing and implementing a pilot test on a tool designed to help healthcare professionals assess the characteristics and quality of mHealth apps used by their patients.
Tan *et al.*, 2022	The last phase (phases 4 and 5 of 5) of an overall project aimed at updating the Enlight Suite tool to assess the quality of mHealth apps. This study aims to evaluate the applicability of the new version.
Woulfe *et al.*, 2022	The aim of this study is therefore to update the Enlight Suite tool to improve its efficacy and applicability internationally. The publication also aims to assess the preliminary validity and reliability of the new version of the Enlight Suite (Modified Enlight Suite) in practice.

The other two references, relating to ISO 82304-2, were used in chapter 2.

4.3.2.1. Purpose of mHealth app assessment

The mHealth app assessment frameworks and methods and the associated criteria are variable depending on their purposes. Three assessment purposes are identified:

- Assessment of an app for the purposes of **validating its quality**, for example, in the context of its development;
- Assessment of apps with a view to **referencing** on a dedicated platform or **labelling/certification**, the objective being to guarantee their quality to users;
- Assessment of mHealth apps with a view to their **funding**. This assessment concerns CE-marked apps and aims to assess their clinical and/or organisational value depending on the country with a view to funding them. This is the case, for example with the DiGA[17] (*Digitale Gesundheitsanwendungen* or Digital Health Applications) process in Germany, the assessment of mobile medical apps by the *Institut national d'assurance maladie-invalidité* (INAMI - National Institute for Health and Disability Insurance) in Belgium,[18] or the *Prise en charge anticipée des dispositifs médicaux numériques* (PECAN - early funding of digital medical devices) and inclusion in the *Liste des activités de télésurveillance médicale* (LATM - List of medical remote monitoring activities) in France.

Only updates and new assessment frameworks introduced after 2021 are detailed in the following paragraphs. All the assessment frameworks identified in the 2021 HAS standard and falling within the scope of this referral are summarised in annexe 4.

[16] Consensus-based Standards for the Selection of Health Measurement Instruments
[17] DiGA
[18] Mobile medical apps: Introduce your request

4.3.2.2. Assessment of mHealth apps with a view to validating their quality

Assessment tools used and associated criteria

Numerous tools are used in the context of assessment of mHealth app quality. Some of these tools have been the subject of validation. For example, the MARS (Mobile Application Rating Scale) and Enlight Suite scales, detailed in annexe 5, are considered to be the most comprehensive and the most used, either as they stand or as a basis for the development of a more customised tool (3-6).

Despite the existence of these validated tools, the studies published in the literature reveal a high level of variability in mHealth app quality assessment tools and the associated criteria, and show that there is currently no tool that can be seen as the gold standard. (3) For example, *Azad-Khaneghah et al*. conducted a systematic review of mHealth app quality assessment tools. They identified 48 different assessment tools, including 23 designed to assess the usability of a mobile health app and 25 strictly to evaluate the quality of an app, without having a precise definition of this term. (7)

Similarly, in their scoping review aimed at analysing different publications assessing criteria used in the context of mHealth app assessment, *Hensher et al.* identified 430 assessment criteria, which the authors distributed between ten assessment criteria domains. Content validity and user experience were the domains most commonly found in the literature. However, it should be noted that none of the assessment tools identified in their publication covered all ten of these domains. (3) Of these 430 criteria, 269 were described as “objective” and 161 as “subjective”, with interpretation left to the discretion of the assessors. (3) Hence, in addition to the variability of assessment tools and criteria, another difficulty is raised for the definition of a gold standard in terms of app assessment: the clarity and applicability of criteria in all assessment frameworks.

This observed heterogeneity is partly due to the fact that there is no consensual definition of the “quality” of an app. (3, 6) There are also a large number of tools developed by the publication authors, who design their tools to assess the characteristics of their apps themselves. In their scoping review, *Hensher et al.* observed that 65% of studies relating to app assessment concern assessment tools or frameworks developed by the authors themselves on the basis of the scientific literature (systematic review, international guidelines) and existing tools, with MARS being the most used. (3) That is because the latter option offers a higher level of flexibility than generic tools. (5)

Finally, one of the challenges for app assessment is to define how to guarantee a sufficient level of quality for users. However, only a minority, in the region of 12%, are developed in collaboration with users and/or healthcare professionals. (8)

Criteria relative to medical content quality

Assessment of the medical content quality is not systematically carried out in the app quality assessment tools. *Azad-Khaneghah et al.* identified two specific tools for the assessment of medical information quality: the *Silberg* scale and the *Brief Discern* scale, (7) detailed in annexe 5. Similarly, some criteria that can be considered to relate to medical content quality are found in the “information” section of the MARS tool (annexe 5). Finally, the DiGA process brings together two criteria in the medical quality content section, which are detailed in annexe 5.

Despite their non-standardised nature, these elements relating to the quality of medical information are avenues for updating MES referencing criteria relating to medical content quality and will be used, where appropriate, to propose adjustments (see 5.3 Updated standard).

Assessment methods and assessors

Since 2021, two new assessment methods have been published:

- The ISYScore-Pro score was published in 2021 and is designed to assess health apps aimed at healthcare professionals. (9) Developed using the Delphi method, the tool includes 17 criteria in three sections: trust, ergonomics and utility;
- In 2022, the Enlight Suite was updated to become the Modified Enlight Suite. (10) The new assessment protocol has seven sections with a total of 32 criteria, including five new criteria in the domains of accessibility and ergonomics.

Different assessment methods are described in the publications retained. Usually, existing tools are based on a point system, such as the 5-point Likert scale or, more rarely, with 3, 4, 7 or 10 points. (3) This scale allows a criterion to be answered by statements representing the assessor's degree of agreement or disagreement. *Hensher et al*. consider that the simpler a tool is considered to be, the lower the risk that responses will be biased. (3) Other assessment methods are based on a scoring system using one or more total scores, averages or other statistical tools. Finally, a non-numerical alternative can be used, in the form of positive or negative responses for each of the criteria. The majority of assessment protocols do not weight the criteria. Where weighting is applied, the highest values are allocated to criteria relating to content, transparency and evidence. (3)

As regards the assessors in the studies, in the majority of cases these are the end users of the apps or the authors of the publication and, in the minority of cases, healthcare professionals or experts in information technology. Generally, the assessment is performed by two people and, in the event of discrepancies, arbitration is performed by a third reviewer. (3)

4.3.2.3. Assessment of mHealth apps with a view to their referencing

Updating of the assessment frameworks identified in the 2021 HAS standard and new international assessment frameworks introduced after 2021

Three main models for the assessment of digital solutions with a view to referencing are identified (annexe 4):

- a **self-declaration model**, like the Swiss one, based on a small number of simple criteria designed to assess technical security, content quality and UX design[19] (user experience);
- a **model based on assessment of a small number of criteria by a public or private body**, as in Spain or Portugal;
- a **model based on the assessment of more than 250 criteria adapted as a function of the complexity and features of digital solutions**, like the ORCHA system (England), which is the most comprehensive tool identified. This assessment, carried out by a team of assessors employed by ORCHA, concerns the most downloaded apps in England every week and is repeated when the apps are updated. It should be noted that access to the app library and requests for app referencing are subject to a charge.

These different models can include an assessment of the clinical and/or organisational benefits when the assessment is associated with a funding process.

[19] The UX design or user experience represents consideration of the quality of the user experience in the design of a digital solution.

The updates and changes to assessment frameworks identified in the 2021 HAS standard, as well as new international assessment frameworks introduced after 2021 with a view to referencing or labelling/certification are summarised in table 5 below.

Table 5: updates/changes to assessment frameworks identified in the 2021 HAS standard and new international assessment frameworks introduced after 2021 with a view to referencing/certification/labelling

Project/body/country	Purpose	Scope	Process/assessment tools and associated criteria	Other information
Label2Enable project[20] (European Commission)	**Labelling process** for app quality based on CEN-ISO/TS 82304-2 (Part 2: Health and wellness apps – Quality and reliability) published in 2021.	Health and wellness apps.	Voluntary process on the part of the developer, with allocation of a label. Scoring tool based on CEN-ISO/TS 82304-2, including 81 questions, of which 67 are specific to quality. Assessment by an accredited body.	Project in the test phase: – 24 apps assessed to date. – 6 accredited bodies in 6 different countries.
DigitalHealthEurope project [21] (European Commission): twinning between Andalusia and Portugal	Creation of a **quality label** for apps. Twinned project between Portugal and Andalusia aimed at establishing a mutual recognition model between Portugal and Andalusia enabling applications recognised in one region to also be recognised in the other. Label objective: to increase public confidence in the use of an app.	Mobile health apps.	Definition of common requirements for the design, use and assessment of mobile health apps between the Andalusian agency for health quality (*Fundación Pública Andaluza Progreso y Salud*), and the Portuguese Ministry of Health (*Serviços Partilhados do Ministério da Saúde*). Requirements based on the processes existing in both countries: *AppSaludable* (Andalusia, 2012) and *MySNS Seleção* (Portugal, 2020) and developed with an expert panel. 31 recommendations developed including the following domains: performance, safety, public utility, information security. App assessment process conducted in a second phase separately, in either Andalusia or Portugal.	Absence of information on the progress status of the project. Heterogeneity per country in the interpretation and semantics of the criteria: the source of the difficulties encountered in the development of the requirements.
mHealth Apps Assessment Framework [22] (Australian Digital Health Agency)	**Referencing process** for mHealth apps with the aim of: – Helping users chose a trustworthy mHealth app. – Guiding healthcare professionals when they recommend or prescribe mHealth apps to their patients.	Mobile health apps in the following fields: – Wellness and healthcare apps. – Apps with medical device status meeting the definition of "software	Assessment by the Australian Digital Health Agency, on a voluntary basis by the developer wishing to have its application referenced. This assessment consists of 4 phases: – Triage: verification that the app is eligible for assessment. This phase also determines the complexity of the app, which will determine the information/evidence that the app developer will have to provide for the assessment. The complexity of the app is assessed based on three criterion domains: • Intended use: medical device status or not.	

[20] Label2Enable
[21] AppSaludable, Digital Health Europe
[22] Assessment framework for mHealth apps

		as a medical device" (SaMD) (definition of the Food and Drug Administration, USA[23]). – Apps with class 1 medical device status meeting the definition of SaMD.	• Intended users: healthcare professionals, patients or specific groups of the population. • Data collection and sharing: personal information collected, data from a sensor or other device, data exchange with a third device. The more complex the app, the more information and evidence will be required. Conversely, less complex apps will have a more rapid assessment process, as is the case for apps having already undergone assessment in another context. – Assessment based on 13 criteria divided into five domains. A score is established for each domain: acceptability, safety and trust, ease of use, data privacy and security, and technical quality assurance. – Publication: assessed apps will then be referenced on a dedicated platform. Several types of information are available on the platform aimed at users: • A description of the app including: the languages available, the name of the app developer, the benefits of the app, alerts, contraindications, restrictions and limitations. • Information relative to the assessment, including the scores allocated (in the form of a star rating from 1 to 4 stars), is displayed on the platform. – Reassessment: the assessment process is automatically repeated every three years. It may be performed before this date if there is a change to the app or changes within the company or if there is a user complaint or an adverse event.	
mHealthBelgium **Belgium**	Referencing of apps. Mobile health apps are categorised on the platform according to 3 levels (M1, M2 and M3).	CE-marked mHealth apps notified to the *Agence fédérale des médicaments et des produits de santé* (AFMPS - Federal	Historically, on the initiative of the Belgian Federal government in 2018, the assessment of apps was conducted by three national authorities depending on the purpose of the assessment (referencing or funding). Since 2024, the assessment of apps with a view to funding or for referencing on the mHealthBelgium platform have been separate. Assessment with a view to referencing is con-	

[23] SaMD

		Agency for Medicines and Health Products).	ducted by the beMedTech sector federations (sector federation for the medical technologies industry) and Agoria (technology industry sector federation). However, the level-based approach is still carried out as a function of criteria or requirements: – Level 1 (M1) defines the basic criteria of the app with a view to referencing on the mHealthBelgium platform: • CE marking • Voluntary notification (as a mobile app) to the AFMPS. • Declaration of conformity with the General Data Protection Regulation (GDPR) – Level 2 (M2) indicates apps for which an application for funding has been made and declared acceptable by the INAMI. The criteria are as follows: • Level M1 criteria. • Technical security and interoperability criteria. • The apps are assessed by the INAMI on the basis of the evidence provided with respect to socioeconomic added value and their importance in the care pathway. – Level 3 (M3) is reserved for requests financed by the INAMI. The criteria are as follows: • Level M1 and M2 criteria. • The apps were assessed by the INAMI and are reimbursed (temporary (M3-) or permanent (M3+) funding).	

Comparison of ISO 82304-2 with other international assessment frameworks

Like the work presented in part 2, other international agencies have compared their assessment framework with the ISO 82304-2 standard.

This is the case with the Australian Digital Health Agency, for example, which highlighted the following points:[24]

- unlike their assessment programme, the standard does not cover the following areas: adaptation of the application to users, culture and end-use;
- the privacy and security, and quality assurance sections are different from those in the standard;
- the safety and trustworthiness, and ease of use sections were globally aligned with the ISO standard.

The Finnish health technologies assessment agency (FinCCHTA) also carried out a comparison between the criteria used in the context of assessment of digital solutions for the social, health and wellness sectors with a view to referencing (Digi-HTA method (annex 4)) and those in ISO 82304-2.[25] This comparison reveals the following points:

- the Digi-HTA method covers a broader scope of digital technologies compared to ISO 82304-2, which focuses on mobile apps;
- in both cases, the assessment process is based on the resources provided by the manufacturer. However, Digi-HTA broadens the assessment by conducting its own analysis of the literature;
- the Digi-HTA initiative includes other aspects not covered by ISO 82304-2, such as the maturity level of the product, its FDA (Food and Drug Administration) classification, its market history, the conduct of any ongoing studies to determine product efficacy, the existence of adverse events associated with its use and the person responsible for their management.

4.3.2.4. Assessment of mHealth apps with a view to their funding

Updates and changes to evaluation frameworks with a view to funding have been introduced since 2021. In Belgium, since 1 October 2023, the *Institut national d'assurance maladie-invalidité* (INAMI - National Institute for Health and Disability Insurance) has assessed mobile medical apps, including remote monitoring apps, with a view to their funding. These must be CE-marked, notified to the AFMPS and have the following features:

- the app enables patients to share information about their health (with or without sensors) with a healthcare provider from their own environment;
- the app enables a healthcare provider to diagnose, apply therapy or monitor a patient remotely via a medical device designed to be used by patients in their own environment.

Two types of funding are possible - temporary or permanent - and determine the application dossier. Temporary funding concerns apps considered to be “promising” but for which some uncertainties still remain. The INAMI assesses the clinical value based on clinical studies and the review of the literature provided by the applicant. The applicant must also provide economic data, based on a budget impact analysis. Applications for funding are voluntary and can be made by manufacturers and distributors,

[24] Assessment framework for mHealth apps, Australian Digital Health Agency, December 2022
[25] Comparison report of Digi-HTA and CEN/ISO TS 82304-2:2021, FinCCHTA, January 2023

scientific associations, professional organisations, members of the multidisciplinary working group responsible for processing applications or hospitals. The assessment is carried out by a multidisciplinary working group made up of permanent members and *ad hoc* members, which draw up a funding proposal, submitted to the consultation bodies concerned and the INAMI Insurance committee in the event of a positive assessment or to the Insurance committee alone in the event of a negative assessment.

It should be noted that since 2024 the INAMI has no longer been involved in the mHealthBelgium platform referencing process (see table 5).

Finally, in 2022, the National Institute for Health and Care Excellence (NICE, UK) also updated its Evidence standards framework for digital health technologies[26] report, aimed at drawing up a reference framework based on the evidence expected for the assessment of digital health technologies and intended for National Health Service (NHS) assessors, technology buyers or local assessors. This update incorporates references to artificial intelligence, covering the management of algorithmic biases and training data.

In collaboration with NICE, the Catalan Agency for Quality of Care and Assessment (*Agència de Qualitat i Avaluació Sanitàries de Catalunya* (AQuAS)) published a reference framework for health technology assessment [27] in 2023 aimed at assessment agencies, digital technology researchers and developers, payers and regulators. This report mentions the same methodology as the NICE report, aimed at establishing the types of evidence required on the basis of a classification of digital health technologies.

In summary

Analysis of the literature shows that there is currently no consensus with respect to the quality of medical content and standardised methods to assess mHealth apps. Nevertheless, some tools have been validated and are being used as a basis for the development of more customised tools for different assessment purposes. That is the case with the MARS and Enlight Suite scales, for example, these being the most frequently used scales to assess apps.

There have also been developments in the methods used to assess mHealth apps with a view to their referencing or certification/labelling, with projects aimed, in particular, at international collaboration. The scopes of the digital services targeted and the assessment dimensions are very heterogeneous. Three main assessment models are observed: a self-declaration model, a model based on the assessment of simple criteria by a public or private body, and a model based on the assessment of numerous criteria depending on the complexity of the digital solutions.

Several agencies have already compared ISO 82304-2 with their own assessment protocols with a view to referencing. These agencies concluded that their own assessment processes were more stringent than the ISO standard.

Finally, the review of international assessment practices did not identify any processes that included an assessment of the interest of applications separate from an assessment with a view to funding. Furthermore, referencing, labelling and certification are used to boost public confidence in the use of mobile apps.

[26] Evidence standards framework for digital health technologies, NICE, 2022

[27] Health Technology Assessment Framework: Adaptation for Digital Health Technology Assessment: User Guide, AQuAS, 2023

5. Conclusion

5.1. Scope of medical content quality criteria

Five MES referencing criteria relative to medical content quality have been updated and two new criteria have been added. The adjustments concern the wording of the criteria and the type of evidence to be produced to justify compliance. In addition, the applicability conditions of each criterion have been detailed.

5.2. Alignment of criteria with ISO 82304-2

As regards medical quality content, comparison of the criteria of the 2021 HAS criteria with ISO 82304-2, the analysis of the literature and the exchanges with stakeholders demonstrate:

- the stricter requirements of the 2021 HAS reference compared to the ISO standard (see chapter 2);
- the limited take-up of the ISO standard by app developers and other agencies, in particular the Australian Digital Health Agency and the FinCCHTA (see chapter 3);
- the uncertainty with respect to the future of the ISO standard, which may not be renewed;
- the limited appearance of the ISO standard in the review of the scientific literature.

Given this information, it does not appear to be necessary to align the criteria relating to medical content quality with ISO 82304-2. Nevertheless, and in accordance with the referral, the work to update the HAS standard took into account the formulation of the ISO standard criteria, where these converged with the 2021 HAS standard.

5.3. Updated HAS standard

The proposals for updating the criteria are listed below.

MES criteria	Updating
Expertise of contributors **(QUA.1.1)**	**Current wording of the MES criterion:** The system must mention and document that the expertise of the persons selecting, validating or writing the medical/health content published in the service is appropriate to the topic covered by the service. This information, along with the conflicts of interests of persons, is available to users of the digital service and easily accessible to all. When medical content is taken directly from the website of an organisation, in particular a national agency or a learned society, for which the information is reputed to be reliable, the name of the organisation and the URL of the website must be indicated. **Proposed new wording:** The medical/health content of the digital service must be selected, validated and/or written by a committee with collective expertise covering the topic of the digital service. The names, qualifications and conflicts of interests of these individuals are available to users and easily accessible. **Proposed new supporting documentation:**

	– Names, qualifications and conflicts of interests of the experts involved in the selection, validation and/or writing of the medical/health content. – Evidence of accessibility of this information to users. This information can be displayed on a dedicated page of the digital service, for example, or in the form of a reference preceding or following the content. **Applicability:** Digital services producing information concerning health, with or without a medical purpose. **Rationale and comments:** Reformulation of criterion QUA.1.1, transfer of the information source notion in criterion QUA.1.2 for clarification of criteria.
Scientific references (QUA.1.2)	**Current wording of the MES criterion:** The system must enable the key sources and scientific references used to develop the medical/health content of the service to be consulted by all. **Proposed new wording:** The medical content of the digital service must comply with the recommendations of organisations providing information considered to be reliable. If it is developed based on scientific references, it must be possible to consult these. All the sources used for drafting medical/health content are easily accessible to users, for example on a dedicated page of the digital service or in the form of a reference preceding or following the content. **Proposed new supporting documentation:** – App developer's compliance undertaking. – List of organisations from which the content is sourced and updated URL of associated websites. – List of scientific references used. – Evidence of accessibility of this information to users. **Applicability:** Digital services producing information concerning health, with or without a medical purpose. **Rationale and comments:** The information source notion from criterion QUA.1.1 has been incorporated in this criterion. In addition, a requirement for compliance of the health information with the recommendations of organisations providing information considered to be reliable has been added. These may be learned societies or public health agencies, for example.
Monitoring process (QUA.1.3)	**Current wording of the MES criterion:** The system must document that the process for monitoring and updating the sources and scientific references used to develop the medical/health content of the service is appropriate to the topic covered by the service. This information is available to users of the digital service and easily accessible to all. **Proposed new wording:** The digital service must include a monitoring process for sources and scientific references useful for the development of medical/health content in order to reflect current knowledge. This information is easily accessible to all. Users are informed when the content consulted was last updated.

	Proposed new supporting documentation: – Evidence of accessibility of this information to users. – Summary of the monitoring and content updating strategy. **Applicability:** Digital services producing information concerning health, with or without a medical purpose. **Rationale and comments:** Addition of the notion of informing users when the content consulted was last updated.
Clinical assessment and level of evidence. **(QUA.1.4)**	**Current wording of the MES criterion:** If the solution has undergone clinical assessment and levels of evidence have been produced, this information is available to users of the digital service and easily accessible to all. **Proposed new wording:** Clinical assessment and level of evidence. **Proposed new wording:** The information relative to existing data documenting the performance, clinical or organisational benefit of the app and opinions issued in the context of requests for public funding cover must be easily accessible to users. Failing this, information relating to the absence of data documenting the clinical or organisational benefit is made available to users of the digital service. This information, as well as evidence, is easily accessible to users, for example on a dedicated page of the digital service. **Proposed new supporting documentation:** Evidence of accessibility of the information made available to users. This information may be: – publications in peer-reviewed scientific journals, protocols, study reports; – public information from trial databases relating to ongoing or upcoming studies or studies for which the results have not been published (for example, clinicaltrials.gov); – a statement indicating the absence of available clinical data documenting the clinical or organisational interest; – the opinion(s) of the CNEDiMTS if the solution has been the subject of an assessment in the context of an application for public funding cover (the most recent if it corresponds to all the indications for which funding has been requested or all the most recent opinions corresponding to each of the indications for which funding has been requested). **Applicability:** Applications producing information concerning health. **Rationale and comments:** This criterion has been updated in order to specify the evidence to be provided to document the performance or benefit. In addition, in the absence of available data, it requires this information to be given to users in the form of a statement indicating the absence of evidence documenting the performance or interest of the application.

Interpretation by healthcare professionals (QUA.1.5)	**Current wording of the MES criterion:** If the service requires interpretation of content for health purposes (health data, scientific content, etc.), the system must guarantee that this is carried out by healthcare professionals with expertise appropriate to the topic covered by the service or by specifically trained competent persons. **Proposed new wording:** The interpretation of personalised health data produced or transmitted by the user must be carried out by professionals whose expertise is appropriate to the topic covered and in accordance with the regulations in force, particularly those relating to the practice of healthcare professions. **Proposed new supporting documentation:** – Summary of the interpretation procedure detailing the qualifications of the professionals involved in particular. – App developer's undertaking to comply with the regulations. **Applicability:** Apps for which the content is subject to interpretation of the information produced by the user (for example, smart objects, questionnaires etc.). **Rationale and comments:** This criterion has been adapted to ensure that apps comply with current regulations. In particular, this addition aims to prevent any practices that could be construed as the illegal practice of medicine.
Proposed new criteria	
Objectives and end-use.	**Proposed wording:** The medical/health content of the digital service must be in line with its end-uses. These must be precisely described and are easily accessible to all, on the home page of the digital service, for example. **Proposed supporting documentation:** – App developer's compliance undertaking. – Description including the medical indications or end-use, the objectives of use and the features of the app. – Evidence of accessibility of this information to users. **Applicability:** Digital services producing information concerning health, with or without a medical purpose. **Rationale / comments:** This criterion was added in order to ensure that the medical content of the digital service is appropriate for its end-use and to provide this information to users. It was proposed on the basis of criterion C12 of the 2021 HAS standard and criterion 16 of section D (Information) of the MARS scale.
Involvement of users	**Proposed wording:** The medical/health content of the digital service must be developed involving representative users from the target population.

Proposed supporting documentation:

Summary of the user consultation strategy for the development of the digital service content (analysis grid, Living Lab, etc.), number of users and/or list of user organisations involved.

Applicability:

Digital services producing information concerning health, with or without a medical purpose.

Rationale / comments:

This criterion was proposed on the basis of criterion C11 of the 2021 HAS standard and adapted based on criterion 5.3.2.2 of ISO 82304-2.

6. Outlook

The main objective of this document is to propose an update of the medical content quality criteria, in the context of a MES digital services referencing process. The information obtained following the analysis of the literature and the exchanges with stakeholders highlighted a need to make changes to the referencing method. In this part, the HAS therefore formulates additional recommendations aimed at guaranteeing the absence of overlap between the different existing assessment processes and at promoting access to information enabling users to assess the quality of the digital services referenced and whether they are appropriate to their needs.

Personalisation of criteria relative to medical content quality

Although the majority of criteria relative to medical content quality defined by the HAS in the 2021 standard were reused as MES referencing criteria, they are currently classed in the “ethics” section. For better clarity, these criteria relative to medical content quality could be grouped together in the specific “medical content quality” section.

Adaptation of the referencing process for apps with medical device status

MES referencing is possible for digital medical devices having already undergone an assessment process, in particular to obtain CE marking. Therefore, for these types of digital services, the referencing criteria already covered by the CE marking requirements are assumed to comply. Consequently, only criteria not covered by CE marking could be assessed for compliance with the MES referencing criteria.

Hence, in its application for referencing of a digital service in the MES service catalogue, the app developer would have to submit the documentation relative to CE marking (CE declaration of conformity or CE certificates delivered by the notified body depending on the MD class, instructions for use in French in accordance with CE marking), as well as the elements concerning compliance with the criteria not covered by CE marking.

Development of useful information aimed at users

Currently, the home page of the MES digital service catalogue presents a brief description of the features and includes a link to a page dedicated to the data privacy policy. To ensure informed use of the service catalogue by users, the HAS recommends that the catalogue home page enable users to understand the checks carried out prior to referencing by sharing some simple information about the process. This page could therefore specify the dimensions covered by the catalogue referencing criteria relating to content quality, ethics, urbanisation, interoperability and security. The fact that although MES referencing does not constitute an assessment of the interest of digital services, it does provide users with information to help inform their choices would also be indicated.

To this end, the MES service catalogue could include the following elements detailed for each digital service:

- optimised display of information relating to the digital service, including a brief description based on the new “Objectives and end-use” criterion, presenting the indications, objectives of use and features;
- information concerning the existence or otherwise of data documenting the interest of the app in accordance with criterion QUA.1.4, in particular access to CNEDiMTS opinions, whether

these are favourable or unfavourable, with a link to consult them. In the event of a favourable opinion, it should also be easy for users to consult the funding conditions;
- information relative to the editorial quality of the digital services, including the names of the organisations from which the medical content is sourced and/or the scientific references used in accordance with criterion QUA.1.2;
- indication of the medical device status, if applicable, what the medical CE mark represents, for example, in the form of a tooltip.

Neutrality of app content

In order to guarantee the credibility of digital services, the MES referencing process could include a neutrality commitment from the app developer. The content circulated should be impartial and independent of the sources of funding for the digital service. The HAS recommends that this be included in the referencing criteria, bearing in mind that the notion of neutrality does not relate exclusively to content quality.

Artificial intelligence and evolution of criteria

The European regulation on AI was recently published and will be progressively phased in. This framework sets out the requirements that will be imposed on manufacturers and users, depending on the level of risk of AI systems. Methodological studies related to this regulation will need to be carried out in the future. The implementation of AI system quality control scheduled by this new regulation does not require modification of the referencing criteria.

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Annexe 1. 2021 HAS standard criteria

Criterion No.	Criteria	Denomination
C01	Information service organisation	Presence of an organisation or an editorial expert committee selecting and validating the information published in the app.
C02	Expertise of authors of content in app	Experts (healthcare professionals, engineers, algorithm experts, professional bodies, patient or consumer associations, etc.) are involved in producing the content available in the app.
C03	Declarations of interest	Declarations of conflicts of interest of the different contributors are available to view for all.
C04	Quote of key sources and bibliographic references	Key sources and references for publications justifying app content are documented and are available to view by all.
C05	Update of key sources and bibliographic references	The process for monitoring and updating key sources and references in relation to publications is documented.
C06	Level of evidence	Where a specific assessment of the product and levels of evidence is available, these suitable references are available to view by all.
C07	Measurement quality in context of use	The measurement quality (contextual robustness) in the setting or context of use is documented and justified with regard to the end-use of the product.
C08	User support	A support is provided and allows users to request assistance for product-use related queries (understanding content and using features). Frequently asked questions are documented and updated.
C09	Human interpretation of health content	In the case of human (non-automated) interpretation of content for health purposes (health data, scientific content, etc.), this is carried out by suitable healthcare professionals for the topic studied or specifically trained competent persons.
C10	Automated interpretation of health content	In the event of interpretation by algorithms intended, for example, to interpret content with a medical remit or for advisory purposes, the user must be informed whether or not AI is included in the algorithm(s) used. The exhaustiveness of the studies assessing the performance level of algorithms should be available to the user.
C11	Involvement of users (patients, professionals, specific parties)	The main users are involved in the different app development phases.

C12	Description of end-use	The main end-use (objective or purpose) of the product is the subject of a precise description available to view by all.
C13	Contraindications, potential risks, limitations of use	Contraindications, potential risks of incorrect interpretation and limitations of use are assessed and documented. This information is available for users to access and view.
C14	Understanding of health content	The app uses terminology that is understandable for the user.
C15	User help/instructions	A user help system for the product is provided to users (contextual help, online help, user manual, tutorial, teaching software, e-learning, etc.). This system supports the user's ability to learn.
C16	Text and image readability and navigation	The navigation and readability of the various media used (text, image, videos) have been tested. The interface allows changes to app readability (change of font or font size, alert colour, etc.).
C17	Error prevention and understanding of information	A tailored alert system for critical decisions following any errors in understanding information by the user is set up to prevent risks or redirect to a healthcare professional.

Annexe 2. Literature search

The search strategy in bibliographic databases is constructed using, for each subject, either thesaurus terms (descriptors) or free-text terms (from the title or the abstract). They are combined with the terms describing the study types.

The table below shows the Medline database search strategy.

Study type/Subject		Search period
	Terms used	
Assessment of mHealth apps		
Meta-analyses and systematic reviews		01/2021 – 03/2024
Step 1	MJMESH.EXACT("Medical Informatics Applications") OR MJMESH.EXACT("Mobile Applications") OR TI("Mobile Applications") OR TI("mobile application") OR TI("mobile app") OR TI("mobile apps") OR TI("smartphone application") OR TI("smartphone applications") OR TI("Smartphone app") OR TI("Smartphone apps") OR TI("app stores") OR TI("Mobile Medical Application") OR TI("Mobile Medical Applications") OR TI("medical apps") OR TI("medical app") OR TI("standalone software") OR TI("health apps") OR TI("health app") OR TI("mhealth") OR TI("mobile health") OR TI("ehealth") OR ((TI(apps) OR TI(app) OR TI(application) OR TI(applications)) AND (TI(mobile) OR TI(smartphone) OR TI(phone) OR TI(watch) OR TI(watchs) OR TI("connected items") OR TI("connected item") OR TI("connected object") OR TI("connected objects")))	
AND		
Step 2	TI(assessment) OR TI(evaluation) OR TI(scale) OR TI(validit*) OR TI(reliabilit*) OR TI(effect) OR TI(effects) OR TI(effectiveness) OR TI(efficacy) OR TI(impact) OR TI(improv*) OR MESH.EXACT("Technology Assessment, Biomedical") OR MESH.EXACT("Software Validation")	
AND		
Step 3	TI(meta PRE/0 analys[*3]) OR TI(metaanalys[*3]) OR TI(systematic PRE/0 literature PRE/0 search) OR TI(systematic* PRE/0 literature PRE/0 review[*3]) OR TI(systematic* PRE/0 overview[*3]) OR TI(systematic* PRE/0 review[*3]) OR DTYPE(meta-analysis) OR DTYPE(systematic review) OR PUB(cochrane database syst rev)	
Assessment of mHealth apps		
Guidelines and consensus conferences		01/2021 – 03/2024
Step 1		
AND		
Step 2		
AND		

Step 4	TI(consensus) OR TI(guideline[*1]) OR TI(position PRE/0 paper) OR TI(recommendation[*1]) OR TI(statement[*1]) OR MESH.EXACT(health planning guidelines) OR DTYPE(consensus development conference) OR DTYPE(consensus development conference, NIH) OR DTYPE(guideline) OR DTYPE(practice guideline)	
Mobile health apps: standards		
		01/2021 – 03/2024
Step 1		
AND		
Step 5	TI(framework) OR TI(frameworks) OR TI(certificat*) OR TI(label*) OR TI(standard) OR TI(criteria) OR TI(scoring) OR TI(frame) OR TI(referential) OR TI(reference)	
Mobile health apps: general aspects		
Meta-analyses and systematic reviews		01/2021 – 03/2024
Step 1		
AND		
Step 3		
Mobile health apps: general aspects		
Guidelines and consensus conferences		01/2021 – 03/2024
Step 1		
AND		
Step 4		

Websites consulted

The websites were queried based on the search procedures specific to each one: consultation of the list of publications and/or query in the website search engine.

In the context of this work, the following websites were consulted.

In French:

- *Académie Nationale de Médecine* [French National Academy of Medicine]
- Canadian public health agency
- *Agence du numérique en santé* - ANS [French digital healthcare agency]
- *Agence nationale de la performance sanitaire et médico-sociale* - ANAP [National agency for the assessment of health and medico-social system performance]
- *Agence Nationale de Sécurité des Médicaments et des produits de santé* – ANSM [French National Agency for Medicines and Health Products Safety]
- *Assistance publique – Hôpitaux de Paris* – APHP [Paris public hospitals]
- *Assurance maladie - Ameli* [French National Health Insurance system]

- *Catalogue et index des sites médicaux francophones* – CISMeF [Catalogue and index of French-language medical websites]
- *Centre fédéral d'expertise des soins de santé* – KCE [Belgian Health Care Knowledge Centre]
- *Centre national de la recherche scientifique* – CNRS [French National Centre for Scientific Research]
- *Collège de la médecine générale* [French College of General Medicine]
- *Collège infirmier français* [French College of Nursing]
- *Collège national des généralistes enseignants* - CNGE [French National College of Teaching General Practitioners]
- *Comité consultatif national d'éthique* – CCNE [National Ethics Advisory Committee]
- European Commission Public Health
- *Conseil national de l'ordre des médecins* – CNOM [French National Medical Association]
- *Conseil national professionnel de pédiatrie* – CNPP [French National Council for Paediatric Medicine Professionals]
- *Conseil supérieur de la santé* - KCE [High Council for Health]
- *Délégation ministérielle au numérique en sante* – DNS [Ministerial Delegation for Digital Healthcare]
- *Direction de la recherche, des études, de l'évaluation et des statistiques* – DREES [Directorate for Research, Surveys, Assessment and Statistics]
- *Direction du numérique* - DNUM [Department for Digital technology]
- *Direction interministérielle du numérique* – DINUM [Interministerial Department for Digital Technology]
- Eurosurveillance
- *France Assos Santé*
- Canadian government
- *Haut Conseil de la santé publique* – HCSP [French High Council for Public Health]
- *Haute Autorité de santé* – HAS [French National Authority for Health]
- Infirmiers.com
- *Institut de recherche et de documentation en économie de la santé* – IRDES [French Health Economy Research and Documentation Institute]
- *Institut national de la santé et de la recherche médicale* – INSERM [French National Institute of Health and Medical Research]
- *Institut national de santé publique du Québec* - INSPQ [Quebec National Institute for Public health]
- *Institut national d'excellence en santé et en services sociaux* – INESSS [Quebec National Institute of Excellence in Health and Social Services]
- French Ministry for Health and Prevention – France
- International Organization for Standardization - ISO
- Quebec telehealth portal
- Health Canada
- *Santé publique France* – SPF [France public health]
- *Santé Publique Ontario* [Ontario public health]
- *Service public fédéral Belgique* – SPF [Belgian Federal Public department]

- *Société française d'anesthésie et de réanimation* – SFAR [French Anaesthesia and Intensive Care Society]
- *Société française de pédiatrie* [French Paediatrics Society]
- *Syndicat national autonome des orthoptistes* - SNAO ([French National Union of Speech Therapists]
- *Syndicat national des ophtalmologistes de France* [French National Union of Ophthalmologists]
- *URPS Médecins d'Occitanie* [Occitanie Regional Union of Physicians]

Other languages:

- Agency for clinical innovation
- Agency for Healthcare Research and Quality – AHRQ
- American Medical association
- Australian College of Rural and Remote Medicine - ACRRM
- Australian Commission on Safety and Quality in Health Care
- Australian government Department of veterans' affairs
- Australian Technical Advisory Group on Immunisation – ATAGI
- Bundesministerium Austria
- Canadian Agency for Drugs and Technologies in Health - CADTH
- Centers for Disease Control and Prevention – CDC
- Centre for Reviews and Dissemination databases - CRD
- Department of health - Australian government
- Digital Health - Australia
- EHealth Network – European Union
- EHealth strategies
- European Centre for Disease Prevention and Control – ECDC
- European medicines agency - EMA
- European Network for Health Technology Assessment - EuNetHTA
- Federal office of public health Switzerland - FOPH
- Food and Drug Administration – FDA
- Global research database
- Government of Canada
- Government Offices of Sweden
- Guidelines International Network – GIN
- Health and human services US department - HHS
- Health Information and Quality Authority – HIQA
- Health resources and services administration – HRSA
- International medical device regulators forum - IMDRF
- International Society for Quality in Health Care – ISQUA
- Medicines and Healthcare products Regulatory Agency - MHRA
- Ministero della Salute - Italy
- Ministry of health – Australia
- Ministry of health - Malaysia

- Ministry of health - New Zealand
- Ministry of social affairs and Health - Finland
- National Health Services - NHS
- National Institute for Health and Clinical Excellence – NICE
- National Institute for Health and Welfare
- National Institute for Public Health and the Environment Netherlands
- National Institute of Public Health - NIPH
- National Institutes of Health – NIH
- Nordic council of ministers
- Nordic innovation
- Pan American Health Organization - PAHO
- Public health England – PHE
- Royal Australian College of General Practitioners - RACGP
- Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU)
- Swedish eHealth agency
- Telehealth HHS – USA
- Terveyden ja hyvinvoinnnin laitos (Finnish institute for health and welfare) – THL
- University of Michigan
- World Health Organization – WHO
- World Health Organization – WHO Europe

Annexe 3. Description of the eight publications selected

Study	Objectives	Methodologies	Results	Comments
Azad-Khaneghah *et al.*, 2021	To review the rating scales used to evaluate usability and quality of mHealth apps, and to compare their purpose, content, psychometric properties and intended target users.	– Systematic review (PRISMA method) – From January 2000 to July 2018 – Inclusion criteria: mHealth app	– 87 studies included – 16 studies aimed at developing an assessment tool – 11 studies aimed at assessing the usability of an mHealth app – 48 assessment tools identified, grouped into 2 categories: • Assessment of usability: - 23 tools identified (40/87 studies) - Domains assessed: ease of use and learning, effectiveness, memorability, error rate and user satisfaction - Majority of the tools identified originally used to assess computers or websites, not specific to mHealth apps; for example: PUEU,[28] SUS • Assessment of quality: - 25 tools identified - No definition of the quality of a mobile health app - 7 tools were developed for a medical domain or a specific disease – Most frequently used tool: MARS (15/87 studies) – Two tools specific to the assessment of quality of information identified: *Silberg scale* and *Discern scale*	– Heterogeneity of assessment criteria
Giebel *et al.*, 2024	To identify quality assessment tools for mHealth apps and determine relevant quality assessment dimensions	– Scoping review from January 2016 to July 2021 – Inclusion criteria: development or description of mHealth app quality assessment methods,	– 70 publications retained – 15 developing a quality assessment method	– Inventory demonstrating a heterogeneity of app quality assessment methods – Extensive use of the MARS scale

[28] Perceived usefulness and ease of use questionnaire

		not specific to a therapeutic domain	– 39 applying a quality assessment method, including 19 applying the MARS tool or a derived tool – Absence of definition of the quality concept – 584 quality criteria grouped into 14 dimensions	
Grau-Corral *et al*., 2021	To develop an instrument to assess mobile apps used in the healthcare context aimed at healthcare professionals and medical personnel (ISYScore-Pro score)	Project in 5 phases: – Composition of an expert group developing the tool – Systematic review of the literature by the group (in Spanish only) – Development of the tool – Validation of the tool using the Delphi method (2 rounds) – Pilot test of the tool with healthcare apps used by the healthcare professionals selected from download platforms	– No assessment tool identified specific to the health apps used by the healthcare professionals – Construction of the tool – 17 questions distributed into 3 assessment domains incorporated into the construction of the tool: trust, utility and interest – Delphi method: 28 people/35 contacted validated the tool a first time then 24/35 validated the tool a second time – Pilot test: 18 apps assessed	– Tool primarily developed by a panel of expert volunteers – Apps used only in Spanish (limited market, smaller than the market including apps in English)
Henscher *et al.*, 2021	Analysis of the different publications assessing the criteria used in the context of assessment of mHealth apps, as well as the scoring and evaluation methods used in this context	– Scoping review (PRISMA[29] method and JBI[30] Manual for Evidence Synthesis for Scoping Review) – From 2011 to April 2020 – Inclusion criteria: mHealth app	– 97 studies included – 65% of studies concern assessment tools or frameworks developed by the authors themselves on the basis of the scientific literature (systematic review, international guidelines) and existing tools, with MARS being the most used – 10 of the most common assessment criterion domains identified, the most frequent are content/information validity and user experience – 430 single criteria identified: • 269 “objective” criteria and 161 “subjective” criteria with interpretation left to the discretion of the assessors	– Heterogeneity of the criteria making up the 10 most frequently identified domains – The assessment and scoring methods are also highly varied and non-standardised – Difficulty identified: the criteria are not always understandable and clear – The simpler the assessment tool is considered to be, the lower the risk that responses will be biased

[29] Preferred Reporting Items for Systematic Reviews and Meta-Analyses

[30] Joanna Briggs Institute

			• Some considered to be too general and vague • Some specific to medical areas – Scoring methods identified: • Point systems most frequently used (34/97 studies including 22 using the 5-point Likert scale) • Combination of point systems, dichotomous and open questions (19/97 studies) • Final score calculated usually based on an average of points (22/97 studies) • No weighting of criteria based on assessment domains in the majority of cases (49/97 studies); in 6/97 studies: weighting or otherwise of criteria based on the importance of assessment domains, defined as a function of the assessment framework objective • Example of the American Psychiatry Association, which has developed a pyramidal mHealth app assessment approach (App Evaluation Framework) – Assessment methods identified: • 2 assessors in the majority of cases (60/97 studies) • The assessors are usually the end-users of the apps (29/97 studies)	
Muro-Culebras *et al.*, 2021	To analyse the quality of the tools that are used to measure the quality of mHealth apps following the COSMIN[31] recommendations	– Systematic review (PRISMA method) – From February 2019 to 31 December 2019 – COSMIN recommendations: – 4 domains that need to be included in the assessment tools	– 10 studies included – 8 assessment tools identified – Tools measuring mHealth app utility: SUS, MAUQ[32] (2 versions depending on how the app is used, as an interaction	– Lack of validation of mHealth app assessment tools: few studies included because most of the studies concern custom-developed tools for the assessment of one app – The authors consider that the MARS scale is the most validated tool for

[31] Consensus-based Standards for the Selection of Health Measurement Instruments

[32] mHealth Apps Usability Questionnaire

		are assessed: reliability, validity (including content validity), reactivity (capacity of a tool to detect changes in measurements), interpretability – According to these recommendations, content validity is considered to be the most important measurement property in assessment tools, since it assesses the relevance of the results obtained using the tools	between patients and healthcare professionals or autonomously), PEUE, Health-ITUES[33] – Tools measuring the overall quality of mHealth apps: iSYScore, MARS, uMARS (version for end-users)	standardised use in the assessment of the overall quality of mHealth apps
Ribaut *et al*., 2024	First phase of an overall project aimed at developing and implementing a pilot test on a tool designed to help healthcare professionals assess the characteristics and quality of mHealth apps used by patients	– 3-step study – Systematic review of the literature in order to identify existing mHealth app assessment criteria – Development of a conceptual app for the assessment of mHealth apps (dimensions assessed and types of evidence) – Compilation of a comprehensive list of criteria for the description and evaluation of mHealth apps – Inclusion criterion: mHealth app	– 128 studies analysed – 142 tools were identified to assess mHealth apps – Tools the most frequently used in the assessment: MARS[34] (25.8%), criteria developed by the investigators (23.4%) and SUS[35] (17.2%) – 205 criteria identified for the assessment of mHealth apps – Most frequently assessed dimensions: usability (45.8%), app quality (26.1%), functionality (12.7%) – The quality of information is assessed in 9.9% of studies – Dimensions selected for development of the assessment tool: content information, functionality, usability, data security and privacy, and performance	– Heterogeneity of the tools and criteria assessed – Absence of consensus with respect to the definition of “app quality” – Study analysis tool (AGREE II[36]) used not very appropriate to the methodology. In fact, this tool is designed to assess a guideline development process. However, the majority of the studies analysed concern the assessment of a specific tool, not the development of guidelines
Tan *et al*., 2022	The last phase (phases 4 and 5 of 5) of an overall project aimed at updating the Enlight Suite	– Collection of opinions via 6 focus groups including healthcare professionals from 3 countries	– 48 healthcare professionals surveyed, 8 per focus group (16/country)	– Absence of inclusion of patients for updating of the assessment tool

[33] Health Information Technology Usability Evaluation Scale
[34] Mobile App Rating Scale
[35] System Usability Scale
[36] Appraisal of Guidelines for REsearch & Evaluation

	tool to assess the quality of mHealth apps. This study aims to evaluate the applicability of the new version of the "Modified Enlight Suite"	(Malawi, South Africa and Ireland) in order to modify/improve the "Modified Enlight Suite" – Validation of changes by healthcare professionals surveyed via an online questionnaire – Inclusion criterion: mHealth app	– 5 questions were added to the "usability" and "content" criteria – Domains of the questions added to the "usability" criterion: timeliness, errors, understandability and access – Domain of the question added to the "content" criterion: cultural appropriateness	– It is planned to test the tool on a single app in a future study – Absence of results relative to the changes made by professionals, which will be the subject of a future publication
Woulfe *et al.*, 2022	To update the Enlight Suite tool to improve its efficacy and applicability internationally To assess the preliminary validity and reliability of the new version of the Enlight Suite (Modified Enlight Suite) in practice	– Delphi method for updating the Enlight Suite: – 2 rounds – 7 mHealth experts included – Inclusion criteria: • Mobile health app • Assessment of the Modified Enlight Suite with the Irish COVID-19 app	– 3 dimensions were added to the first version of the Enlight Suite: cultural appropriateness (e.g. languages available in the app), readability and accessibility	

Annexe 4. International health app assessment agencies or bodies

Body/Country	Purpose	Scope	Target	Type of criteria	Inclusion process
Ehealth Suisse **Switzerland**	Referencing on an open-access web platform	Mobile health app	– Patients and carers – Healthcare professionals	– Transparency – Fitness for purpose – Risk proportionality – Ethical acceptability – Legal compliance – Content validity – Technical suitability – Ease of use – Resource efficiency	– Self-declaration (free text) – Publication on an open-access web platform
Digi-HTA assessment **Finland**	Referencing on the University of Oulu website on an open-access basis	Digital products and services for the healthcare, social and wellness sectors	– Users	– CE marking – Efficacy – Costs – Safety – Usability and accessibility – Security and data protection	– Assessment by the Finnish Coordinating Centre for Health Technology Assessment on the basis of a dossier submitted by the manufacturer, supplemented by an analysis of the literature and expert opinions. Score allocated to each assessment dimension producing an overall score – Assessment conclusion valid for 3 years – Assessment published on the University of Oulu website – Several types of information available on the platform aimed at users: – Description of the app including: a summary of its features, the languages available, CE certificate, information security management system of the app, name of the app developer – Information relative to the assessment, including the overall score of the app and the scores for each dimension reported in the form of colours (red, orange, yellow, green depending on the points allocated)

AppSaludable (Andalusia) and MySNS Selecçao (Portugal)	Twinning between Portugal and Andalusia to create a **quality label** for apps aimed at establishing a mutual recognition model between Portugal and Andalusia enabling apps recognised in one region to also be recognised in the other. The objective of this label is to increase public confidence in the use of an app	Mobile health app	– Patients and carers – Healthcare professionals	– Definition of common requirements for the design, use and assessment of mobile health apps between the Andalusian agency for health quality (*Fundación Pública Andaluza Progreso y Salud*), and the Portuguese Ministry of Health (*Serviços Partilhados do Ministério da Saúde*) – These requirements are based on the processes existing in both countries: *AppSaludable* (Andalusia, 2012) and *MySNS Selecção* (Portugal, 2020). They were developed by a panel of experts – 31 recommendations were developed including the following domains: performance, safety, public utility, information security	– The app assessment process is then conducted in a second phase separately, in either Andalusia or Portugal – Absence of information on the progress status of the project
ORCHA **England**	Referencing and certification on a paying web platform	Mobile health app	– Patients and carers – Healthcare professionals	– Criteria based on the domain and the purpose of the app: – Data security – Medical content – Usage and accessibility	– Assessment by ORCHA – Allocation of a use risk score – Publication on a paying web platform
TIC Salut Social **Spain (Catalonia)**	Certification with referencing on an open-access web platform	Mobile health app	– Patients and carers – Healthcare professionals	– Certification criteria based on CEN ISO/TS 82304-2 and divided into 4 categories – Medical content and functionality – Robustness – Ease of use, accessibility and design – Data security and privacy	– Assessment by an expert committee – Information displayed on the website: – Medical domain – Target user – Description – Developer – Cost – Last version and date

Australian Digital Health Agency **Australia**	**Referencing process** for mHealth apps with the aim of: – Helping users chose a trustworthy mHealth app – Guiding healthcare professionals when they recommend or prescribe mHealth apps to their patients	Mobile health apps in the following fields: – Wellness and healthcare apps – Apps with medical device status meeting the definition of SaMD – Apps with class 1 medical device status meeting the definition of SaMD	– Patients and carers – Healthcare professionals	– Acceptability – Safety and trust – Ease of use – Privacy and security – Quality assurance	– Assessment by the Australian Digital Health Agency, on a voluntary basis by the developer wishing to have its application referenced. This assessment consists of 4 phases: – Triage: verification that the app is eligible for assessment. This phase also determines the complexity of the app, which will determine the information/evidence that the app developer will have to provide for the assessment. The complexity of the app is assessed based on three criterion domains: – Intended use: medical device status or not – Intended users: healthcare professionals, patients or specific groups of the population – Data collection and sharing: personal information collected, data from a sensor or other device, data exchange with a third device – The more complex the app, the more information and evidence will be required. Conversely, less complex apps will have a more rapid assessment process, as is the case for apps having already undergone assessment in another context – Assessment based on 13 criteria divided into five domains. A score is established for each domain: acceptability, safety and trust, ease of use, data privacy and security, and technical quality assurance – Publication: assessed apps will then be referenced on a dedicated platform. Several types of information

					are available on the platform aimed at users: – Description of the app including: the languages available, the name of the app developer, the benefits of the app, alerts, contraindications, restrictions and limitations – Information relative to the assessment, including the scores allocated (in the form of a star rating from 1 to 4 stars), is displayed on the platform – Reassessment automatically performed every 3 years, or before this date if there is a change to the app or changes within the company or if there is a user complaint or an adverse event
Tallinn University of Technology **Estonia**	Referencing	Mobile health applications	– Patients and carers – Healthcare professionals	– General information and objectives – Security and privacy – Clinical or historical evidence – Interoperability and interface	– Assessment based on public information and responses provided by the company – App developer's comments on the assessment project – Publication of the decision
mHealthBelgium **Belgium**	Referencing of apps on a platform. Mobile health apps are categorised on the platform according to 3 levels (M1, M2 and M3)	CE-marked mHealth apps notified to the *Agence fédérale des médicaments et des produits de santé* (AFMPS - Federal Agency for Medicines and Health Products)	– Users	– However, the level-based approach is still carried out as a function of criteria or requirements: – Level 1 (M1) defined by the basic criteria of the app with a view to referencing on the mHealthBelgium platform: – CE marking – Voluntary notification (as a mobile app) to the AFMPS – Declaration of conformity with the General Data Protection Regulation (GDPR) – Level 2 (M2) indicates apps for which a request for funding has	– Assessment conducted by the beMedTech sector federations (sector federation for the medical technologies industry) and Agoria (technology industry sector federation) – Publication on an open-access web platform

				been made and declared acceptable by the *Institut national d'assurance maladie-invalidité* (INAMI - National Institute for Health and Disability Insurance). The criteria are as follows: – Level M1 criteria – Technical security and interoperability criteria – The apps are assessed by the INAMI on the basis of the evidence provided with respect to socioeconomic added value and their importance in the care pathway – Level 3 (M3) reserved for requests funded by the INAMI, with the following criteria: – Level M1 and M2 criteria – The apps were assessed by the INAMI and are reimbursed (temporary (M3-) or permanent (M3+) funding)	
Assessment of digital health technologies by the National Health Service (England)	Referencing on the NHS website and apps on an open-access basis	Any new digital technologies. Examples: digital health technologies aimed at personnel and patients, health apps, medical technologies and devices with an associated app, systems, web portals, etc.	– Users	– Based on Digital Technology Assessment Criteria for health and social care (DTAC[37]) – Criteria divided into 5 main domains: – Clinical safety: products are assessed to ensure that clinical safety measures are in place and that organisations undertake clinical risk management activities to manage this risk – Data protection: products are assessed to ensure that data protection and privacy is “by design” and that individuals’ rights are protected	NA

[37] DTAC

				– Technical security: products are assessed to ensure that they are secure and stable – Interoperability: products are assessed to ensure that data are communicated accurately and rapidly, while remaining safe and secure – Usability and accessibility: products are allocated a compliance score after being assessed with respect to best practice and the NHS service standard	
Evidence standards framework for digital health technologies [38]), National Institute for Health and Care Excellence (NICE) (England)	Aimed at National Health Service (NHS) assessors, buyers or local assessors with a view to funding or purchase of digital health technologies	Digital health technologies, CE marked or otherwise, according to the assessor	– Patients – Healthcare professionals	– Types of evidence required based on a classification of digital health technologies – 21 evidence standards divided into 5 groups related to the life cycle and based on a risk classification (3 risk tiers: A, B and C): – Design factors: 9 evidence standards related to the design process of the technology that impact its value to the health and care system. Includes its safety and reliability – Describing value: 4 standards that apply across all risk tiers that must provide the information to construct the value proposition of the technology – Demonstrating performance: 2 standards on performance expectations – Delivering value: 2 standards to demonstrate the value for money of the technology (all risk tiers)	NA

[38] Evidence standards framework for digital health technologies, NICE, 2022

				– Deployment: 3 standards make it possible to guarantee that the claimed benefits can be delivered in practice	
Assessment of mobile medical apps, *Institut national d'assurance maladie-invalidité* (INAMI - National Institute for Health and Disability Insurance), Belgium	Funding	Mobile medical app, CE marked, notified to the AFMPS, and which: – enables patients to share information about their health (with or without sensors) with a healthcare provider from their own environment – enables a healthcare provider to diagnose, apply therapy or monitor a patient remotely via a medical device designed to be used by patients in their own environment – Other requirements: apps must meet a set of technical eligibility criteria	– Patients	– Assessment of the clinical benefit based on clinical studies and the review of the literature provided by the applicant – The applicant must also provide economic data, based on a budget impact analysis	– Voluntary submission of an application. This application can be made by: manufacturers and distributors, scientific associations, professional organisations, members of the multidisciplinary working group responsible for processing applications, hospitals – Assessment by a multidisciplinary working group made up of permanent members and ad hoc members – Funding proposal by the multidisciplinary working group: – Temporary funding: – Temporary funding concerns apps considered to be “promising” but for which some uncertainties still remain – At the instigation of and in liaison with the applicant, the multidisciplinary working group develops a funding and evidence collection proposal – Permanent funding (for a period of 3 years): multidisciplinary working group develops a care process funding proposal – Validation of funding by the *Conseil supérieur de la santé* (High Council for Health) and consulting bodies

DiGA mechanism **BfArM, Germany**	Funding	CE-marked mHealth apps	– Patients and carers	– CE marking – Medical content technical criteria – Benefit to the health system (medical and/or organisational)	– Self-declaration of technical criteria and medical content by the developer – Verification of self-declaration by the BfArM and request for evidence if required – Assessment of the benefit to the health system by the BfArM – Publication on an open-access web platform

Annexe 5. Frequently identified assessment tools

Mobile App Rating Scale (MARS)

Sections	Questions
A – Engagement	Entertainment: Is the app fun/entertaining to use? Does it use any strategies to increase engagement through entertainment (e.g. through gamification)?
	Interest: Is the app interesting to use? Does it use any strategies to increase engagement by presenting its content in an interesting way?
	Customisation: Does it provide/retain all necessary settings/preferences for apps features (e.g. sound, content, notifications, etc.)?
	Interactivity: Does it allow user input, provide feedback, contain prompts (reminders, sharing options, notifications, etc.)? Note: these functions need to be customisable and not overwhelming in order to be perfect.
	Target group: Is the app content (visual information, language, design) appropriate for your target audience?
B – Functionality	Performance: How accurately/fast do the app features (functions) and components (buttons/menus) work?
	Ease of use: How easy is it to learn how to use the app; how clear are the menu labels/icons and instructions?
	Navigation: Is moving between screens logical/accurate/appropriate/uninterrupted? Are all necessary screen links present?
	Gestural design: Are interactions (taps/swipes/pinches/scrolls) consistent and intuitive across all components/screens?
C – Aesthetics	Layout: Is arrangement and size of buttons/icons/menus/content on the screen appropriate or zoomable if needed?
	Graphics: How high is the quality/resolution of graphics used for buttons/icons/menus/content?
	Visual appeal: How good does the app look?
D – Information	Accuracy of app description (in app store): Does app contain what is described?
	Goals: Does app have specific, measurable and achievable goals (specified in app store description or within the app itself)?
	Quality of information: Is app content correct, well written, and relevant to the goal/topic of the app?
	Quantity of information: Is the extent coverage within the scope of the app; and comprehensive but concise?
	Visual information: Is visual explanation of concepts – through charts/graphs/images/videos, etc. – clear, logical, correct?
	Credibility: Does the app come from a legitimate source (specified in app store description or within the app itself)?
	Evidence base: Has the app been trialled/tested; must be verified by evidence (in published scientific literature)?

E – Subjective quality	Would you recommend this app to people who might benefit from it?
	How many times do you think you would use this app in the next 12 months if it was relevant to you?
	Would you pay for this app?
	What is your overall star rating of the app?

Enlight Suite

Sections	Questions
Quality assessment	Usability Assesses the ease of learning how to use the service and the ease of utilising it properly
	Visual design: Assesses the look and feel of the program, the visual quality of the Graphical User Interface (GUI).
	User engagement Assesses the extent to which the service's design attracts users to utilise it.
	Content: Assesses the content provided or learned while using the service.
	Therapeutic persuasiveness: Assesses the extent to which the service is designed to encourage users to make positive behaviour changes OR to maintain positive aspects of their life.
	Therapeutic alliance: Assesses the ability of the program to create an alliance with the user in order to effect a beneficial change.
	General subjective evaluation Examines the program's general potential to benefit its target audience based on rater's subjective evaluation.
Checklist	Credibility: Assesses the degree to which the product / developers can be trusted.
	Evidence based program: Assesses the quality of empirical research supporting the program's efficacy (a separate measure that is part of program's credibility).
	Privacy explanation: Assesses which actions are taken to enable users to understand how well their privacy is maintained by the program, that is, in order to enable users to determine whether and how to use it.
	Security: assesses whether appropriate actions are taken to protect the privacy/confidentiality of data collected or transmitted.

Silberg scale (specific to medical content quality)

Sections	Questions
Authorship	Cite authors and contributors. Cite their contributions and their credentials.
Attribution	Cite references and sources of information for all content. This should be listed clearly along with any relevant copyright information.
Disclosure	The owner(s) should be clearly identified in full; the same applies for sponsors, any patronage, advertising, advertorials, commercial funding arrangements or similar support,

	and any potential conflicts of interest. This also includes arrangements linking and referring to other sites for a financial reward. This type of standard should also be extended to discussion forums.
Currency	Content publication and update dates.

Brief DISCERN (specific to medical content quality)

Questions
Is it clear what sources of information were used to compile the publication?
Is it clear when the information used or reported in the publication was produced?
Does it describe how each treatment works?
Does the publication describe the benefits of each treatment?
Does it describe the risks of each treatment?
Does it describe how the treatment choices affect overall quality of life?

DiGA process, medical content quality criteria

Questions
Is the digital health app based on reliable medical knowledge? Is it clear what sources of information were used to compile the publication?
Is the health information provided to the user by the digital health app appropriate?

Bibliographic references

1. Hoogendoorn P, Versluis A, van Kampen S, McCay C, Leahy M, Bijlsma M*, et al.* What makes a quality health app. Developing a global research-based health app quality assessment framework for cen-iso/ts 82304-2: Delphi study. JMIR Formative Research 2023;7.
https://dx.doi.org/10.2196/43905

2. Neal D, Engelsma T, Tan J, Craven MP, Marcilly R, Peute L*, et al.* Limitations of the new ISO standard for health and wellness apps. Lancet Digit Health 2022;4(2):e80-e2.
https://dx.doi.org/10.1016/S2589-7500(21)00273-9

3. Hensher M, Cooper P, Dona SWA, Angeles MR, Nguyen D, Heynsbergh N*, et al.* Scoping review: Development and assessment of evaluation frameworks of mobile health apps for recommendations to consumers. J Am Med Inform Assoc 2021;28(6):1318-29.
https://dx.doi.org/10.1093/jamia/ocab041

4. Tan YY, Woulfe F, Chirambo GB, Henn P, Cilliers L, Fadahunsi KP*, et al.* Framework to assess the quality of mHealth apps: a mixed-method international case study protocol. BMJ Open 2022;12(10):e062909.
https://dx.doi.org/10.1136/bmjopen-2022-062909

5. Muro-Culebras A, Escriche-Escuder A, Martin-Martin J, Roldan-Jimenez C, De-Torres I, Ruiz-Munoz M*, et al.* Tools for evaluating the content, efficacy, and usability of mobile health apps according to the consensus-based standards for the selection of health measurement instruments: Systematic review. JMIR Mhealth Uhealth 2021;9(12):e15433.
https://dx.doi.org/10.2196/15433

6. Giebel GD, Speckemeier C, Schrader NF, Abels C, Plescher F, Hillerich V*, et al.* Quality assessment of mHealth apps: a scoping review. Front Health Serv 2024;4:1372871.
https://dx.doi.org/10.3389/frhs.2024.1372871

7. Azad-Khaneghah P, Neubauer N, Miguel Cruz A, Liu L. Mobile health app usability and quality rating scales: a systematic review. Disabil Rehabil Assist Technol 2021;16(7):712-21.
https://dx.doi.org/10.1080/17483107.2019.1701103

8. Ribaut J, DeVito Dabbs A, Dobbels F, Teynor A, Mess EV, Hoffmann T, De Geest S. Developing a comprehensive list of criteria to evaluate the characteristics and quality of ehealth smartphone apps: Systematic review. JMIR Mhealth Uhealth 2024;12:e48625.
https://dx.doi.org/10.2196/48625

9. Grau-Corral I, Pantoja PE, Grajales Iii FJ, Kostov B, Aragunde V, Puig-Soler M*, et al.* Assessing apps for health care workers using the ISYScore-Pro Scale: Development and validation study. JMIR Mhealth Uhealth 2021;9(7):e17660.
https://dx.doi.org/10.2196/17660

10. Woulfe F, Fadahunsi KP, O'Grady M, Chirambo GB, Mawkin M, Majeed A*, et al.* Modification and validation of an mhealth app quality assessment methodology for international use: Cross-sectional and eDelphi studies. JMIR Form Res 2022;6(8):e36912.
https://dx.doi.org/10.2196/36912

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The following professional bodies, patient associations and user representatives were involved in this work, as stakeholders:

- Endomind
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- *France Assos Santé*
- France Biotech
- Numeum
- User representative on the MES referencing committee
- *Syndicat National de l'Industrie des Technologies Médicales* [French national medical technologies industry union] (SNITEM)
- *Union nationale de familles et amis de personnes malades et/ou handicapées psychiques* [French national union of families and friends of patients with mental illnesses or disabilities] (UNAFAM)

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SNITEM

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Abbreviations and acronyms

AFMPS	*Agence Fédérale des Médicaments et des Produits de Santé* [Federal Agency for Medicines and Health Products]
BfArM	*Bundesinstitut für Arzneimittel und Medizinprodukte* [Federal Institute of Medicines and Medical Devices]
CNAM	*Caisse nationale de l'assurance maladie* [National Health Insurance Fund for salaried workers]
CNEDiMTS	*Commission Nationale d'Evaluation des Dispositifs Médicaux et Technologies de Santé* [National Committee for the Evaluation of Medical Devices and Health Technologies]
DiGA	*Digitale Gesundheitsanwendungen* [Digital Health Applications]
DMP	*Dossier Médical Partagé* [Shared Medical Record (SMR)]
DNS	*Délégation au Numérique en Santé* [Ministerial Delegation for Digital Health]
DTAC	Digital Technology Assessment Criteria for health and social care
FDA	Food and Drug Administration
FINCCHTA	Finnish Coordinating Centre for Health Technology Assessment
HAS	*Haute Autorité de Santé* [French National Authority for Health]
AI	Artificial Intelligence
INAMI	*Institut National d'Assurance Maladie-Invalidité* [National Institute for Health and Disability Insurance]
ISO	International Organization for Standardization
LATM	*Liste des Activités de Télésurveillance Médicale* [List of medical remote monitoring activities]
MARS	Mobile App Rating Scale
MES	*Mon Espace Santé* [online health space]
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PECAN	*Prise En Charge Anticipée des dispositifs médicaux Numériques* [early funding of digital medical devices]
GDPR	General Data Protection Regulation
SaMD	Software as a Medical Device
SNITEM	*Syndicat National de l'Industrie des Technologies Médicales* [French national medical technologies industry union]
UNAFAM	*Union nationale de familles et amis de personnes malades et/ou handicapées psychiques* [French national union of families and friends of patients with mental illnesses or disabilities]

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