HAUTE AUTORITÉ DE SANTÉ

Assessment and Improvement of Practice

Good Practice Guidelines on Health Apps and Smart Devices (*Mobile Health* or *mHealth*)

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This document and additional resources can be downloaded from:
www.has-sante.fr

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Abbreviations and Acronyms

AFCDP	Association française de normalisation [French Association for Standardisation]
AFNOR	Association française des correspondants à la protection des données à caractère personnel [French Association of Data Protection Correspondents]
ANSM	Agence nationale de sécurité du médicament et des produits de santé [French National Agency for Medicines and Health Products Safety]
ANSSI	Agence nationale de la sécurité des systèmes d'informations [French National Agency for Information Systems Security]
Apps/SDs	Mobile applications/smart devices
ASIP-Santé	Agence des systèmes d'information partagés de santé [Agency for Shared Health Information Systems]
BMI	Body mass index
CE	CE marking (compliance with requirements)
CERT	Computer Emergency Response Team – also known as CSIRT (Computer Security Incident Response Team)
CERT-FR	Computer Emergency Response Team for France
CNIL	Commission nationale de l'informatique et des libertés [French Data Protection Authority]
CSRF	Cross-site request forgery
EBIOS	Expression des besoins et identification des objectifs de sécurité [Expression of needs and identification of security objectives]
ENISA	European Union Agency for Network and Information Security
EU	European Union
FAQ	Frequently asked questions
GDPR	General Data Protection Regulation
GTC	General terms and conditions
HAS	Haute Autorité de Santé
HDS	Hébergeur de données de santé [Health data host]
HMI	Human-machine interface
HON	Health On the Net Foundation
ICT	Information and communications technology for education
ISO	International Organization for Standardization
kg	kilogram
MD	Medical device
mHealth	Mobile health
OS	Operating system
OWASP	Open Web Application Security Project
PAS	Publicly available specification
PD	Personal data
PDA	Personal digital assistant
RCT	Randomised controlled trial
RGAA	Référentiel général d'accessibilité pour les administrations [General Accessibility Guidelines for Government Agencies]
RGI	Référentiel général d'interopérabilité [General Interoperability Guidelines]
RGS	Référentiel général de sécurité [General Security Guidelines]
SMS	Short message service
TLS	Transport Layer Security
W3C	World Wide Web Consortium
XSS	Cross-site scripting (sometimes abbreviated as CSS)

Foreword

This contribution from HAS aims to **provide guidance for, promote use of and increase confidence in** health apps and smart devices, by supplying **good practice guidelines for manufacturers and evaluators** (evaluating bodies, consumer associations or medical professional organisations), who can use them for their own assessments.

These guidelines cover apps and smart devices that have no stated medical purpose. In other words, they apply specifically to the "grey area" of apps or smart devices that have potential effects on health but are not medical devices. Medical devices, as defined by European Directive 93/42/EEC which leads to CE marking, are excluded.

These guidelines do not replace the law or regulations concerning medical devices (as defined by European Directive 93/42/EEC which leads to CE marking), data protection or consumer protection. The good practice defined in these guidelines should be applied without prejudice to the regulations in force.

These HAS good practice guidelines are not an assessment tool for reimbursement, or a professional recommendation.

Mobile health (mHealth) opens up new options for improving monitoring of chronic conditions and allowing patients to take a more active role in their care. It could also help with developing the prevention aspect of our healthcare system. Academic research into big data in health may likewise contribute to medical progress.

In this context, the Haute Autorité de Santé has produced good practice guidelines on mobile applications and smart devices (apps/SDs) in health.

Evaluating mHealth apps and smart devices draws on many areas of good practice. The Haute Autorité de Santé (HAS) has the remit to produce guidelines on domains that correspond to its objectives, which are:

- improvement in the quality of care (clinical benefit, organisation);
- medical information quality (comprehensiveness, neutrality, accuracy and whether medical information is up-to-date);
- patient safety (categorised by level and type of risk, based on the intended use and main target user of the app/SD);
- health evaluation (impact on public health);
- coordination of care and resulting interoperability (information architecture);
- cost-effectiveness (economic efficiency).

Two additional domains, which depart from the HAS strategic issues but are intrinsically related to this topic, were also studied: these are protection of privacy and cybersecurity. They have been partially covered in these guidelines thanks to contributions from the French National Agency for Information Systems Security (ANSSI) and the French Data Protection Authority[1] (CNIL).

Other more technical areas of assessment that also concern mHealth are not addressed in this guide, such as:

- **telecommunications**[2] from a technical point of view and as regards the security of information[3], its transmission or the complete process related to accessing, storing and transmitting health data;
- **hosting**[4] the data collected (Act of 4 March 2004);
- **data security/reliability**[5] from a **data or signal processing** and **metrology** perspective;
- **reliability of algorithms** and formulas;
- etc.

These guidelines are a first step in the processes of evaluating and designing mHealth apps and smart devices. They will be subject to change as the sector develops.

These guidelines will be supplemented by materials for users (healthcare professionals and individual users), to be published at a later date.

1. www.cnil.fr/linstitution/actualite/article/article/quantified-self-m-sante-le-corps-est-il-un-nouvel-objet-connecte/
2. www.wi6labs.com/blog/fr/2013/12/13/quelle-technologie-radio-pour-les-objets-connectes-premiere-partie/
3. esante.gouv.fr/sites/default/files/Guide_Pratique_Dispositif_Connecte.pdf
4. esante.gouv.fr/services/referentiels/securite/hebergement-faq
5. internetactu.blog.lemonde.fr/2015/03/07/les-applications-de-sante-en-questions/

It should be noted that in Europe, a good practice guide was proposed in a green paper published in 2014[6] and is expected to come out in 2017[7]. This will supplement the code of conduct[8] and ongoing processes of interoperability and standardisation[9] from the European eHealth Action Plan 2012-2020.

6. ec.europa.eu/digital-single-market/news/green-paper-mobile-health-mhealth
7. ec.europa.eu/digital-single-market/en/news/new-eu-working-group-aims-draft-guidelines-improve-mhealth-apps-data-quality
8. ec.europa.eu/digital-single-market/en/privacy-code-conduct-mobile-health-apps
9. ec.europa.eu/digital-single-market/en/interoperability-standardisation-connecting-ehealth-services

1. Background

Our thinking on how to assess information and communication technology (ICT) in the sphere of health is evolving. We are entering a transitional period between assessment models for "general" software, which may perform a number of different functions, and apps, which are **small programs that meet specific or rapidly changing niche needs** (1).

This paradigm shift from the assessment or regulation/certification of "general" programs to the assessment of small specialised programs brings with it the challenge of appropriate and specific evaluation tools that can be flexible over time.

These small programs are better at meeting needs "on the ground" and they seek to be more relevant. They also offer new possibilities for targeted promotion or regulation activities in high-stakes areas of public health and/or health economics. There is a marked difference from certifying websites, and ultimately, what we have learned there only partially applies to the issue of health apps and smart devices.

The convergence of many concepts (ICT, big data, etc.) is related to the **rapid development** (2) **of the technologies** used (miniaturisation, smartphones, data streaming). The first effective uses of "patient-centred mobile health" involved sending SMS messages to help patients remember to take their medicines [Park systematic review (3)]. In 2014, "advanced" apps were developed for the same purpose with a calendar, history, data server, etc. [Bailey systematic review on apps for medication self-management (4)].

Questions about the trustworthiness and safety of apps/SDs are raised by the latest developments:

- **emergency medical information** apps (with blood group, allergies, consent to organ donation, etc.) that can be accessed direct from the lock screen of the user's smartphone;
- **advice/recommendations** received by users through apps or smartphone-connected devices (automatically via an algorithm or from a healthcare professional);
- the use of smartphone **geolocation** functions to orient users;
- data collected to create **practice profiles** for healthcare professionals;
- etc.

In all these situations, users should be able to enjoy **products that do not harm their health** and that provide **at least equivalent benefit** to pre-existing options.

Assessing the quality of health apps/SDs appears to be necessary because of the diverse nature of products available on a fast-growing market.

For users, the assessment needs are easy to describe:

- For patients or healthy users, could this app/SD be helpful to my health and in what way, compared with products that already exist?
- For healthcare professionals, how can I answer patients' questions about the apps/SDs they are using? Which apps/SDs should I use in my practice and recommend/prescribe to my patients?
- For patient associations and professional bodies, what should we select/develop/promote for our community?

For the manufacturers responsible for design and development, there are more specific questions:

- How do we make sure that users' needs are taken into account?
- Has the app/SD been developed with due regard to transparency, quality, confidentiality and data security?
- Have any risks or threats been identified, addressed and monitored?

Between 2002 and 2012, the quality assessment of mHealth apps/SDs has changed from a technological assessment to a public health impact evaluation. The most studied diseases and health problems include diabetes, obesity, mental health conditions, smoking and chronic conditions (5).

Although take-up by patients and healthcare professionals is variable and some barriers or contributory factors have been identified (6), the idea of personalised medicine and self-tracking (the *quantified self*) is growing. De la Vega discusses the evolving concept of prescribing an app/SD for a specific patient with a specific problem (1).

According to the Canadian Advanced Technology Alliance (7), five topics should be discussed in this field:

- awareness and education;
- access to personal health data;
- reimbursement models for clinicians;
- certification for mHealth apps;
- managing the gap between innovation and adoption.

1.1 Definitions and Concepts: Apps and Smart Devices

The World Health Organization (8) defines the term ***Mobile Health (mHealth)*** as *"medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices. "*

As regards **smart devices** (9), no specific definition has been identified. In this document, they are defined as devices connected to the internet that can collect, store, process and send data or that can take specific actions based on information received.

Aungst (10) identifies four types of apps:

- **Mobile app:** Software that is operated on a mobile device and fulfils particular function(s).
- **Native mobile app:** Software that comes preinstalled on a mobile device (e.g. software that operates a device's built-in camera).
- **Downloadable mobile app:** Software that is not preinstalled on a device and must be downloaded from an external source (usually a mobile app store).
- **Web-based app:** Software that connects to an internet portal and displays content on a mobile device. Requires an internet connection.

The term "app" is recommended for scientific publications in English (11). Agarwal (12) offers a specific checklist, mERA, for evaluating articles in the field.

mHealth is a sub-segment of eHealth that partially overlaps with the fields of telemedicine and the quantified self (13).

1.2 Classifications Found in the Literature

Various classifications are described in the literature. We cite some to illustrate the directions this sector is taking.

Aungst classification (10)

Aungst's proposed classification has four categories, each divided into four subcategories:

- **Patient centred:** health promotion, patient communication, health tracking and medication reminders;
- **Clinician centred:** electronic health record and electronic prescribing, productivity, communication, medical calculator;
- **Reference:** disease reference, clinical reference, drug reference, medical literature;
- **Education:** general medical education, specialist medical education, continuing medical education, patient education.

Classification by Mosa (14)

Mosa classifies apps based on medical practice:

- seven categories for healthcare professionals: disease diagnosis, drug reference, medical calculators, scientific literature search, clinical communication, Hospital Information System client applications, medical training. One "general" category for other apps;
- education apps for students;
- apps for patients: disease management with chronic illness.

Classification by Yasini (15)

Yasini used a field survey to define 31 categories (evaluated based on 567 "health" apps in French, consisting of 218 for healthcare professionals and 352 for the general public).

These categories are: clinical guidelines, scientific popularisation, synthesis of medical knowledge, health news, searching a database (drug, image, nutrition, etc.), books, communication among the general public, communication between healthcare professionals and institutions, communication among the public and healthcare professionals, communication among healthcare professionals, calculating or interpreting data, checking patient records, decision support systems, remote monitoring and/or collection of data, using the mobile device as a diagnostic or measurement tool, calculating fees, accounting support, schedule management, job searching, support with coding/pricing medical procedures, managing drug stock, locating a healthcare service, interaction with a healthcare organisation/pharmacy/insurance company, looking for information on healthcare professionals/institutions, case reports, serious games, educational questions.

Classification by Mobile World Capital and the Catalan Agency for Health Information, Assessment and Quality (AquAS) (16):

Mobile World Capital (MWC) and the Agència de Qualitat i Avaluació Sanitàries de Catalunya (Catalan Agency for Health Information, Assessment and Quality – AquAS) suggest an assessment framework with five levels of risk in a risk matrix that categorises intervention-specific risk (from "references/guides" to "monitor/alert") and person-specific or patient-specific risk.

Other classifications:

- Labrique (17) categorises apps based on 12 types of function that can be managed by a smartphone;
- For apps in a specific field (cancer), Bender (18) describes eight defined app categories (awareness, information about disease and treatment, fundraising, early detection, promoting an organisation, disease management, prevention, peer support);
- Yetisen (19) defines three main categories that can be used to aid regulation (preventive medicine and health promotion; portable diagnosis and monitoring instruments; data management, medical training and mobile payment);
- Hussain (20) lists types of health apps and health app assessments and suggests next steps for patients, developers, agencies, etc.;
- Cook (21) is one example of a review on apps intended to improve melanoma diagnosis. Few criteria are discriminating, but Cook suggests classifying apps based on their potential users (all patients, high-risk patients, students).

1.3 mHealth Assessment in Different Countries

Various organisations offer or have offered services that list, certify or register health apps/SDs. A non-exhaustive list is provided for information (Table 1).

Table 1. Non-exhaustive list of sites that evaluate health apps/SDs in various countries (in alphabetical order)

Country	Name	Organisation/Provider
Germany	AppCheck[10]	*ZTG Zentrum für Telematik und Telemedizin GmbH*
Germany	HealthOn[11]	*Sanawork*
Spain (Andalusia)	AppSaludable: Catálogo de aplicaciones móviles de salud[12]	*Andalusian Agency for Healthcare Quality*
USA	Zur Institute[13]	*Zur Institute*
USA	Eat right[14]	*Academy of Nutrition and Dietetics*
USA	Happtique[15]	*Greater New York Hospital Association* *NB: programme suspended*
USA	iMedicalApps[16] iprescribeapps.com[17]	*iMedicalApps*
USA	UF Diabetes Institute[18]	*UF Diabetes Institute*
France	AppScript[19]	*IMS Health*
France	DMD santé[20]	DMD santé
France	GPM e-santé[21]	Groupe Pasteur Mutualité
France	Medappcare[22]	Medappcare
France	Sanofidiabete[23]	SANOFI & DMD santé
Netherlands	Royal Dutch Medical Association (KNMG)[24]	*Medical App Checker*
UK	UK National Health Service (NHS) Apps Library[25]	NHS NB: programme suspended
UK	myhealthapps.net[26]	*Patient View*

10. www.appcheck.de - 11. www.healthon.de -12. www.calidadappsalud.com/distintivo/catalogo/13. www.zurinstitute.com/mentalhealthapps_resources.html - 14. www.eatright.org/appreviews - 15. www.happtique.com/home - 16. www.imedicalapps.com/about - 17. iprescribeapps.com - 18. diabetes.ufl.edu/my-diabetes/diabetes-resources/diabetes-apps - 19. www.imshealth.com - 20. www.dmd-sante.com - 21. www.gpm.fr/toutes-les-news.html?id=10093 - 22. www.medappcare.com/conseil-scientifique - 23. www.sanofi-diabete.fr/Accueil/Menu/Guide-des-applications-diabete - 24. www.knmg.nl/over-knmg/contact/about-knmg.htm - 25. apps.nhs.uk/review-process/# - 26. myhealthapps.net/about

Most platforms for assessing apps/SDs use an analysis grid that covers different fields and draws on the expertise of healthcare professionals, users and technical risk analysis, with a focus on cybersecurity, data protection, legal compliance, etc. Medical devices (MDs) are not within the remit of these assessments. These systems seek to evaluate the "grey area" of apps and smart devices that have no stated medical purpose.

1.3.1 Regional or National Systems for Assessment

The World Health Organization (WHO) has written up the results of a survey on eHealth in Europe. As regards mobile health, 22% of countries (10 countries) state they have set up a system to evaluate the quality, safety and reliability of mHealth apps (22).

Since 2013, with AppSaludable, the Andalusian Agency for Healthcare Quality has offered a catalogue of apps that meet the agency's 31 recommendations. In 2015, almost 17% of the region's population was using at least one of these apps.

On the other hand, Happtique and NHS Choices have stopped or suspended their registry activities after security problems concerning some apps listed on their websites (23).

On an international level, there appears to be no consensual approach to assessing mobile apps or smart devices that are not declared as medical devices (24-29).

However, according to Canada Health Infoway, there are several situations where regulation may be needed (2), especially for anything that might influence users' or healthcare professionals' decisions about health and wellbeing (27, 30-35).

The Australian hub that lists the different approaches in different developing countries offers practical examples of integrating apps[27] for developing countries.

In the EU, a European Commission working group is writing a good practice guide on guaranteeing the reliability and safety of mobile apps and smart devices. This document is expected in early 2017[28]. HAS took part in the working group and provided information from this guide.

1.3.2 Scales and Scores for Assessment

On an individual level, the assessment scale found most often in the literature is the Australian MARS score (Mobile App Rating Scale). This is used for publications that evaluate health apps. This rating scale is reproduced in Appendix 1 for information. A non-exhaustive list of other scales and scores is provided for information below:

- ABACUS[29] (36);
- Gonnermann (37) suggests three levels: overall assessment (10 criteria), content (6 criteria) and study level (assessment depends on the methodology and follows guidelines for publication);
- McMillan (38) proposes 62 questions;
- Albrecht (39) offers a reporting checklist;
- Salber (40) has a guide for clinicians with six practical criteria:
  - evaluate whether your patients have already used medical apps, wireless medical devices, or any other digital health tools;
  - know what type of information your patients get from their digital health technologies and what they do with it;
  - understand whether the app, device or program is safe and whether it provides accurate information;
  - try the app/SD yourself;
  - evaluate whether you and your patient feel that the app/SD will improve communication and the doctor/patient relationship;
  - determine whether the app fits into your workflow;
- Murfin (41) offers the KYA (Know Your Apps) model: go to the source, sponsors, references, protocol evaluation, updates;
- Chan (42) suggests an assessment for the mental health field:
  - usefulness dimension (4 criteria);
  - usability dimension (5 criteria);
  - integration/infrastructure dimension (5 criteria);
  - and categories;
- Huckvale (43) proposes an evaluation for asthma apps. This is an adaptation of the HON guidelines and eight principles;
- Safavi (44) provides a list of ten principles and nine checklists to help developers protect data confidentiality.

27. www.uq.edu.au/hishub/wp25
28. ec.europa.eu/digital-single-market/en/news/new-eu-working-group-aims-draft-guidelines-improve-mhealth-apps-data-quality
29. libguides.library.arizona.edu/c.php?g=122854&p=802639

The American Health Information Management Association (AHIMA) has a tool for patients and the general public called "just think APP" [30]. The acronym stands for Advice, Privacy and Personal data. This document evaluates and lists questions to ask yourself with advice to follow.

1.4 Measuring Impact and/or Effectiveness

Health apps and smart devices have been being developed for less than ten years, which explains why publications on measuring their impact or therapeutic effect size are still limited.

1.4.1 Systematic Reviews on mHealth

Payne (45) evaluated the main areas where apps are used in a systematic review. Apps that aim to change behaviour (diet, addictions, etc.), promote physical activity or monitor depressive illness are the most commonly studied. In terms of methodology, sample sizes are most often under 100. Effects were found in all the fields studied. Higher-powered studies are needed.

Free (46) carried out a meta-analysis on improving healthcare with similarly modest results. Hamine (47) showed improved adherence for chronic diseases.

The literature search did not look for cost studies specifically, as this was not the aim of the work requested. There are some publications on this subject, which show a tendency towards reducing healthcare costs (48-50) A more comprehensive analysis would need to be conducted on the topic of cost-effectiveness.

1.4.2 Some Results for Health Problems

A non-exhaustive selection of publications on the efficacy of health apps/SDs for different health problems is presented to give an overview of the current range of publications on specific subjects. The types of app/SD examined in these studies are heterogeneous (some are medical devices, others are not).

▶ Diabetes

Russell-Minda (51) conducted a systematic review on diabetes and smart devices that measure blood glucose and physical activity. The results indicate better glycaemic control and improved management.

Positive results are also found in a Chinese meta-analysis by Liang (better glycaemic control) (52) and in a systematic review by Holtz (53).

In another systematic review, Gray (54) recommends risk assessment and external validation of risks. This emphasises the specific teaching and health education efforts that are needed in this domain.

▶ Physical activity and obesity

Liu (55) conducted a meta-analysis on the impact of apps on physical activity and weight loss. BMI and weight (-1.44 kg; 95% CI: -2.12 to -0.76) were improved.

Other studies (56, 57) highlight the beneficial role of apps in this field or for recommendations in the field of paediatric obesity (58).

In a systematic review, Bort-Roig (59) highlights the apps/SDs that have the most impact: creating physical activity profiles, setting goals, real-time feedback, support networks, and online consultation with experts. This publication complements a previous study by Fanning (60) on quality criteria for effective apps/SDs in this field.

▶ Asthma

A 2013 Cochrane systematic review on asthma (61) was unable to conclude whether apps/SDs have any benefit in this field, because the studies are too heterogeneous and few in number.

In 2015, Huckvale (62) demonstrated a change in the quality of asthma apps between 2011 and 2013, which seems to suggest that the sector is developing in short cycles.

1.5 Legal Aspects of Assessing Health Apps and Smart Devices

The design and distribution of mHealth smart devices must comply with existing (French and European) legal requirements, particularly as concerns medical devices, data exchange and processing personal health data.

30. myphr.com/HealthLiteracy/MX7644_myPHRbrochure.final7-3-13.pdf

1.5.1 Compliance with Legal and Regulatory Requirements for Medical Devices

Some apps/SDs may be considered medical devices (MDs).

Medical devices are defined in article L. 5211-1 of the French Public Health Code as "*any instrument, apparatus, appliance, material, product, with the exception of products of human origin, or other article, whether used alone or in combination, including the accessories and software necessary for its proper application, intended by the manufacturer to be used in humans for medical purposes and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. Software intended by the manufacturer to be used specifically for diagnostic or therapeutic purposes is also a medical device*".

The French National Agency for Medicines and Health Products Safety (ANSM) is the competent authority for MDs, especially as regards market surveillance and "vigilance". On its website[31], it lists some key aspects that help to determine whether a health app is classed as a medical device or not, based on its purpose.

It also indicates the consequences and the procedure for marketing apps that are classed as MDs (CE marking, risk analysis, producing technical documentation, etc.)[32].

1.5.2 Compliance with Legal and Regulatory Requirements for Data Sharing and Personal Data Processing

The requirements on collecting and processing data apply whenever the data processed by apps/SDs relate to a physical person who is identified or could be identified, directly or indirectly[33].

The following specific principles must be respected when personal data is processed:

- **Principle of purpose:** Before any personal data is collected or used, the data controller must tell the individuals concerned precisely what the data will be used for;
- **Principle of data relevance:** Only data that is strictly necessary for achieving the objective may be collected. This is the principle of minimising collection. Data controllers must not collect more data than they actually need. They must also be conscious of the sensitive nature of some data;
- **Principle of limited-duration data storage:** Also known as the right to be forgotten. Once the objective behind collecting the data is achieved, there is no longer any reason to store them and they must be deleted. The duration of storage must be defined in advance by the data controller, taking into account any obligations to keep certain data;
- **Principle of data security and confidentiality:** Data controllers must take all measures necessary to guarantee that data they collect are secure and confidential, in other words to ensure that only authorised people access them. These measures must be based on the risks relating to the file (sensitive data, objective of processing, etc.);
- **Principle of respecting people's rights:** Data about people may only be collected on the essential condition that they have been informed of this operation. People also have certain rights that can be exercised with the organisation that holds their data: the right to access these data; the right to correct them; the right to oppose their use; the right to be forgotten (have personal data deleted); the right to data portability, allowing individuals to easily send their data to another data controller; the right to be informed if their data are hacked;
- Health data[34], which are particularly sensitive, are subject to stricter control.

In addition, apps/SDs that can exchange or share information must guarantee data security.

Furthermore, sharing or exchanging a person's health data requires their express consent, obtained in advance. Individuals must be able to change or withdraw their consent at any time.

CNIL, the French authority responsible for overseeing data protection, helps professionals to comply with the law and offers several guides on the collection and use of personal data, particularly by healthcare professionals[35].

31. ansm.sante.fr/Produits-de-sante/Dispositifs-medicaux
32. ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/Logiciels-et-applications-mobiles-en-sante/%28offset%29/1
33. French Act No. 78-17 of 6 January 1978 on information technology, data files and civil liberties; Regulation (EU) 2016/679 of the European Parliament of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (this regulation will apply to all Member States of the European Union from 25 May 2018 with no need to transpose it).
34. "Data concerning health" are defined by the EU regulation of 27 April 2016 as "personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status".
35. www.cnil.fr

1.5.3 Compliance with Provisions on Hosting Personal Health Data

Apps/SDs that require personal health data to be hosted on behalf of the natural or legal persons responsible for producing or collecting this data or on behalf of patients themselves must comply with article L. 1111-8 of the French Public Health Code.

The French Agency for Shared Health Information Systems (ASIP), whose remit includes developing a range of products and services for structuring eHealth, publishes guides and information on these matters on its website[36].

36. esante.gouv.fr

2. Good Practice Guidelines

The good practice guidelines on health apps and smart devices were produced via several steps: literature analysis, independent working group, review group and input from stakeholders. A project outline explains the origin of this document and how it was created.

2.1 Areas of Assessment

A sizeable literature review was performed by Riezebos (63) in 2014. This cites various authors who have sought to assess health apps/SDs. A peer review system organised by an online journal (Appendix 2) was created based on this literature analysis[37]. Its summary table of different authors was used to list all the criteria described in the literature for mHealth assessment.

From this document, the working group selected the relevant criteria and structured them by category and subcategory. A total of five categories and 14 subcategories were accepted for the good practice guidelines in this document.

List of five categories and 14 subcategories for assessment in the good practice guidelines:

- **Informing users**
  - Description
  - Consent
- **Health content**
  - Design of initial content
  - Standardisation
  - Generated content
  - Interpreted content
- **Technical content**
  - Technical design
  - Data flow
- **Security/Reliability**
  - Cybersecurity
  - Reliability
  - Confidentiality
- **Usability/use**
  - Usability/design
  - Acceptability
  - Integration/import

For each of these categories and subcategories, assessment criteria have been compiled based on the criteria proposed by Riezebos (63) and suggested by the working group or external experts. They are described, justified and placed in context with concrete examples.

2.2 Tailoring the Scope of Assessment

Apps/SDs have different levels of risk. Lewis (64) defines different types of risk to improve evaluation; this approach leads to various assessment scenarios.

This observation suggests that it may not be feasible to produce a single set of guidelines that can cover the wide range of apps/SDs and their different risk levels.

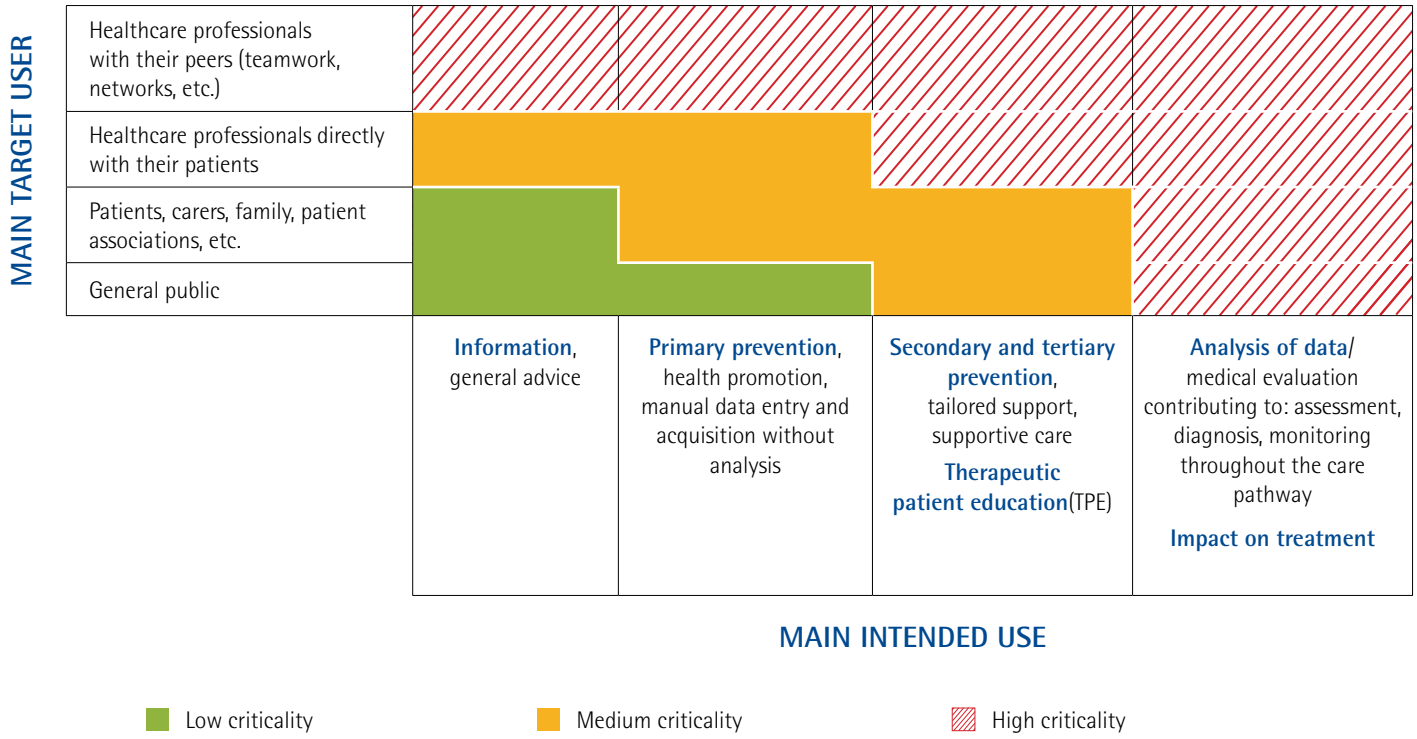
One solution is to use weighting, allowing the assessment to be adapted to the standard required for the app/SD in question.

A risk matrix (Table 2) was produced so that the list of criteria in the guidelines can be tailored. It is weighted based on the **main user** and the **main intended use** declared for the app/SD.

Green represents the lowest standard required and **red** the highest standard. The yellow level is intermediate.

37. tinyurl.com/appsform

Table 2. Tailoring the guidelines using a risk matrix



A product that has an impact on treatment must always be secure, regardless of its target audience. In addition, although the matrix allows for it, this type of product should absolutely not be aimed at the general public.

2.2.1 Description of Risk Matrix Rows and Columns

The main user axis is divided into four categories: the general public, patients and carers, healthcare professionals directly with patients, and healthcare professionals with peers.

On this axis, the highest standard required concerns healthcare professionals, because their decisions are likely to affect a large number of patients. Products must be even safer.

The main intended use axis is divided into four categories: information/advice, primary prevention, secondary prevention/ therapeutic patient education, and finally data analysis and impact on treatment.

On this axis, the highest standard required concerns the analysis of data that impacts on users' assessments and diagnoses and impact on treatment, versus general information.

The proposed weighting is not intended to downgrade the quality of the assessment. It helps evaluators to select assessment criteria and a security level that are appropriate to how the product is used.

▶ Arbitrary example A: "mypill" app

An app that manages patients' medication use would be considered to have a high required standard. All criteria (except those that are not applicable) should be used for the assessment.

▶ Arbitrary example B: "myasthma" app

An information app would be considered to have a lower required standard. A limited selection of criteria should be used.

Note that whatever the weighting, some criteria are essential to maintaining product quality. This particularly concerns the "compulsory" criteria, which are based on the regulations.

2.2.2 Criteria Levels

This document is a good practice guide. It has been produced with the aim of improving the quality of apps/SDs available on the market. Apart from criteria based on legal and regulatory requirements, which are "compulsory", the criteria included in the guidelines are considered either "recommended" or "desirable" depending on the above weighting. In other words, the same non-compulsory assessment criterion may be either "desirable" or "recommended" depending on the standard required, allowing the guidelines to be adapted to the type of app/SD evaluated.

Concrete examples are used to illustrate the criteria throughout the guidelines.

2.2.3 How to Select and Weight Guideline Criteria

In practice, assessment criteria from the guidelines are selected using the following steps:

- **Determine the main target user** (normally indicated by the designer or manufacturer);
- **Determine the main use** of the app/SD (normally indicated by the designer or manufacturer);
- **Find the position on the risk matrix to select the standard required** based on the two previous answers (e.g. a general information website for patients corresponds to the green level);
- **Select criteria from each category and subcategory** based on the standard required/criticality level (use the table provided with this document or the summary table for each category in the next section);
- **Exclude criteria that do not apply** because they are not relevant to the specific app/SD (e.g. criteria on measurement accuracy cannot be used to assess a health information app);
- **Evaluate the "compulsory" criteria in the five assessment categories**. If legal or regulatory requirements are not met, the assessment is stopped at this stage. Remember that these guidelines are not a substitute for medical device regulations and legal compliance is required;
- **Evaluate** the "recommended" and "desirable" criteria. Some criteria require a risk analysis, which cannot be conducted without the support of competent individuals;
- **Compile the results of assessing** the criteria and summarise (with any specific recommendations for improvement).

Again, remember that these guidelines are not a substitute for medical device legislation, and legal compliance is required. Moreover, these guidelines do not aim to provide an exhaustive list of the legal and regulatory requirements applying to health apps and smart devices.

The following sections describe the list of criteria.

2.3 Category: Informing Users

The informing users category (Table 3) is the first category that should be evaluated before the assessment is continued.

Table 3. List of criteria related to informing users

SUBCATEGORY	TITLE	STANDARD REQUIRED/CRITICALITY LEVEL FOR APPS/SDS		
		Low	Medium	High
Description	Product name	C	C	C
	Product definition (version and environment)	R	R	R
	Price and any subscriptions or in-app purchases	C	C	C
	Sources of funding	R	R	R
	Assessment	R	R	R
	Author credits	C	C	C
	Contact details (publisher)	R	R	R

R Recommended C Compulsory

SUBCATEGORY	TITLE	STANDARD REQUIRED/CRITICALITY LEVEL FOR APPS/SDS
Consent	Legal formalities	
	Compulsory information	
	Compulsory consent to data use (separate from GTCs)	
	Consent changed and accessed at any time	
	Correction and deletion at any time	

R Recommended C Compulsory

2.3.1 *Subcategory: Description*

▶ Product name

Is the exact name of the product[38] stated accurately in promotional materials and online stores?

Justification: The name should prevent any confusion with similar names. Fake apps that try to imitate a well-known product are found in many sectors (job searching, fake antivirus software, etc.). Users should watch out for phishing attempts where similar designs or names are used for a malicious purpose.

Example: The product can be selected unambiguously in an online store and users can crosscheck with corroborating information.

▶ Product definition (version and environment)

Is the product version accessible (version and revision numbers, version date), with a list of major changes made in this version (developments and fixes) and the usage environment (operating system, internet browsers, platform, etc.)?

Justification: Different versions may have different functionality. Users should be able to identify the version(s) that meet their needs. Security patches or other improvements may also inform users that certain older versions should no longer be used for various reasons (inter-app conflict, measurement error, etc.). Similarly, the usage environment should be appropriate for users' devices.

Example: Users are informed that previous versions of a product had operational problems or errors, so that they can use an appropriate and accurate version that meets their needs and is suitable for their devices.

▶ Price and any subscriptions or in-app purchases

Are the price and any subscriptions or purchases of additional or built-in products (in-app purchases) displayed transparently and explained to users?

Justification: Some products cannot be used without a subscription, and the financial model of other apps relies on in-app purchases. The built-in payment or billing function(s) must be transparent, explicit and consultable by anyone.

Example: Users may find themselves tied in to long-term contracts (after an initial "one month free") or having to pay unspecified running costs (e.g. paid access to a mobile network). The "real" cost of using the product must be explicit. Users must be informed of additional services available in the app at extra cost.

38. In the rest of the document, the term "product" is used to designate an mHealth app alone or a smart device that interfaces with an app.

▶ Sources of funding

Are sources of funding and details of funders documented[39] and available for consultation?

Justification: The source of funding may influence decision making or encourage the distribution of content that is biased towards maintaining or promoting the funder's activity, depending on the accuracy and impartiality required by the product. Funding sources should not influence the neutrality or credibility of the product.

Example: An app that claims to inform/educate patients with a chronic disease may present the treatment options in a way that financially favours the funder. The sources of funding should be reported.

▶ Assessment

Are the type(s) and nature of assessment(s) already undertaken documented, if up to date?

Justification: Different types and natures of assessment (external evaluation, online rating, quality audit, CE marking, etc.) should be available and transparent.

Example: The owner of a product could manipulate the assessments undertaken to promote it abusively. To prevent this, the owner makes available all assessments carried out that are valid for the current version of the product.

▶ Author credits

Are the names and roles of contributors and any copyrights documented and can they be consulted by anyone?

Justification: Information sources must be explicit so that the role of each contributor is known. Copyrights[40] (for images, videos, other sources) must be published because a designer could take credit for part of a competitor's information or for images that they do not own.

Example: The origin of an app's content is stated and users can see the contributing authors and image credits.

▶ Contact details (publisher)

Are contact details documented and available for consultation, including response times between enquirers and the publisher?

Justification: Users should be able to contact someone if they have any questions about using the product and if there is no hotline. A physical address and telephone numbers or electronic contact details (email, form, etc.) should be made available to everyone.

Example: An app function is not activated and the user emailed support several days ago, although the published response time is within 48 hours. The product's publisher implements a procedure to improve follow-up of technical or administrative requests from users.

2.3.2 Subcategory: Consent

▶ Legal formalities

Is the purpose of data processing defined, explained and legitimate?

Have formalities concerning personal data processing and the health data hosting been addressed?

Justification: The formalities above are legal requirements.

Example: An app has been registered with the French Data Protection Authority (CNIL) and its host is an approved health data host (HDS/HADS); a privacy risk study has been carried out.

▶ Compulsory information

Does the provision of compulsory information follow the good practice principles below?

For developers:

- Have an explicit confidentiality policy that is easy to access;
- Before use, obtain informed consent on access to sensitive information (e.g. location, contact list, calendar, photos, videos, etc.) if the platforms and operating systems do not do this systematically;
- Improve communication and coordination with any advertising companies (or analysis companies) used by developers, to harmonise information on data collection;
- Work towards standards put into place by various organisations.

39. "Documented" is used to mean that a formal record exists and can be consulted on demand.
40. www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006069414

Is compulsory information also provided in the case of change(s) to the general terms and conditions (GTCs)?

Justification: Some products may have access to smartphone content such as emails, instant messages, lists of phone calls, address books, calendar records, social networks, browsing history, saved photos/videos, system preferences, location, microphone access, camera access, miscellaneous files, etc. For developers, the "*privacy by design*" principle is critical for all user personal data; failure to comply may jeopardise trust in the app.

Designers must provide explicit information on these aspects.

Example: An app requests access to the user's location without specifying when this will be accessed or that the camera will be used at the same time. The product's designer implements a procedure to improve their provision of compulsory information.

▶ Compulsory consent to data use (separate from GTCs)

Is the consent to data use explicit and separate from the general terms and conditions?

Before use, is informed consent obtained on access to sensitive information (e.g. location, contact list, calendar, photos, videos, etc.) if the platforms and operating systems do not do this systematically?

Is compulsory consent also obtained in the case of change(s) to the GTCs?

Justification: Consent to access general data must be obtained.

Consent to access specific smartphone data must be explicit.

Example: Users must approve a notification or choose a specific setting before their camera, location or other smartphone content is used.

▶ Consent changed and accessed at any time

Can the user's consent to data collection and processing be displayed and managed?

Justification: Users have the right to change their consent at any time. This also means it must be managed separately from the general terms and conditions (which are accepted on the first use only).

Example: A setting can be accessed to amend consent.

▶ Correction and deletion at any time

Can users exercise their right to correct and/or delete their data?

Justification: Users have the right to change their data or delete it at any time, which also means that consent must be given separately from the general terms and conditions (accepted on the first use only).

Example: A setting can be accessed to change or delete personal data.

2.4 Category: Health Content

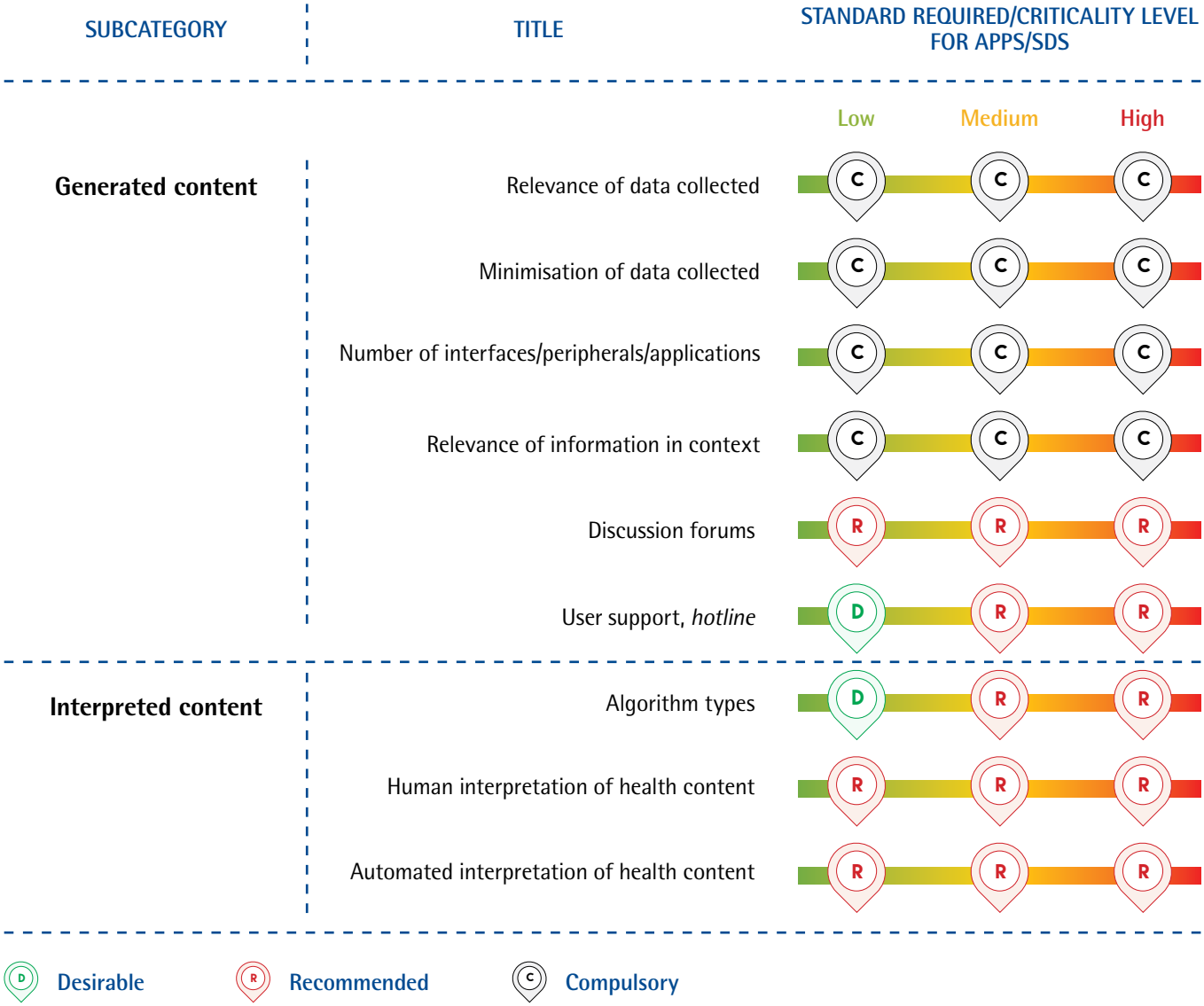
The health content category (Table 4) assesses the reliability of information. It covers content generated by the product and content interpreted when an algorithm or a professional from the sector analyses and processes generated content.

BinDhim (65) published a survey showing that 77% of users do not check the credibility of information.

Table 4. List of criteria related to products' health content

SUBCATEGORY	TITLE	STANDARD REQUIRED/CRITICALITY LEVEL FOR APPS/SDS
		Low / Medium / High
Design of initial content	User involvement (patients, professionals, specific people)	D / R / R
	Methodology of user requirements engineering	D / R / R
	Information department structure	D / R / R
	Expertise of content authors	R / R / R
	Declarations of interests	R / R / R
	Citing key sources and bibliographic references	R / R / R
	Updating key sources and bibliographic references	R / R / R
	Level of evidence	R / R / R
	Description of intended use	C / C / C
	Product language	R / R / R
	List of terms/glossary	D / D / D
Standardisation	Interoperability: semantic standards, standard terminologies	D / R / R
	Data precision and reproducibility	D / R / R
	Data granularity	C / C / C
	Information loss (through aggregation, compression, etc.)	D / R / R
	Measurement performance in the environment of use	D / R / R
	Possibility of synching data	D / D / D

D Desirable R Recommended C Compulsory



2.4.1 Subcategory: Design of Initial Content

▶ User involvement (patients, professionals, specific people)

Are key users involved in the specification, design and acceptance phases and the maintenance phase (adjustments following changes or fixes)? Is this criterion documented?

Justification: Transparently involving the different stakeholders in the design process is an indication of quality.

Example: An app that teaches handwashing technique is created in collaboration with people who deliver face-to-face training.

▶ Methodology of user requirements engineering

Is the methodology of user requirements engineering documented (identification, definition, analysis/hierarchy of requirements)?

Justification: Assessing users' needs can improve the product design goals. Using a tool or method to collect, analyse and structure these needs helps to make the product more relevant.

This assessment can identify the key user of the product. Is this criterion documented?

Example: External evaluators have access to the methodology used by the designer (analysis grid, L'Ecritoire, Living Lab, etc.).

More information:

Hilliard (66) carried out a survey to examine users' needs in the context of adult cystic fibrosis. Jibb (67) developed an algorithm for cancer pain; this led to the design process for an adolescent cancer app. User motivation should be studied further (68, 69). Silow-Carroll (70) conducted a survey on patients' requirements; the answers depended on age and specific needs.

▶ Information department structure

Is there a validation committee or a body that manages the provision of information? Is this criterion documented?

Justification: The task of writing and managing content available on the product should be supported by a validation committee that ensures quality information is published.

Example: An app that provides summaries of good practice guidelines for healthcare professionals has set up a peer review committee to check that the summaries do reflect the original guidelines.

▶ Expertise of content authors

Are experts (healthcare professionals, engineers, professional bodies, patient or consumer associations, etc.) involved in providing content for the product? Is this criterion documented?

Justification: The level of expertise of the product's content authors is an indication of quality. Peer recognition or endorsement by professional associations or bodies improves the credibility of the product's content.

Examples: Some healthcare professionals, supported by their scientific association, have created an information platform on what to do during an asthma attack. The app indicates the level of expertise of the specialists involved.

A patient association is creating an information app and FAQ for patients' families and carers. It contacts a professional association involved with the disease to get an outside opinion on the app's content.

▶ Declarations of interests

Can the contributors' declarations of interests concerning the product be consulted by anyone?

Justification: Declarations of interests are an indication of quality for users and external evaluators. Conflicts of interest may result in bias, which could affect the product's reliability.

Example: External evaluators perform spot checks to make sure that these declarations are truthful or to check for any bias resulting from interests.

▶ Citing key sources and bibliographic references

Are the key sources documented, with references to publications that support the app/SD's content, and can they be consulted by anyone[41]?

Justification: In healthcare, citing bibliographic sources with an objective selection of the best data available is a required indication of quality. The list of references should be easy to access.

Example: Sources may be cited within the app, on a resources website, in external documentation, etc.

▶ Updating key sources and bibliographic references

Are the processes for monitoring and updating key sources and publication references documented?

Justification: Monitoring the literature allows the information provided by the app/SD to be updated and adapted. The date when this information was updated should be cited.

Example: A database alert is set up and abstracts from specific journals are monitored and dated for an information app on a rare disease.

▶ Level of evidence

If there is a specific assessment of the product and levels of evidence, can these references be consulted by anyone?

Justification: HAS has produced guides to critical analysis of the literature, grading levels of evidence and assessment methodology[42,43,44,45,46].

Some apps/SDs have been studied in randomised controlled trials (RCTs) and some types of app have been included in systematic reviews. These references are important and should be accessible to justify the product's value.

"Alternative" approaches to mHealth assessment have also been considered, such as:

- clinical integration (use of the product);
- behaviour change associated with using the product;
- etc.

41. "Can be consulted by anyone" means that the information can be accessed without making a purchase or installing the app.
42. www.has-sante.fr/portail/upload/docs/application/pdf/analiterat.pdf
43. www.has-sante.fr/portail/upload/docs/application/pdf/2013-06/etat_des_lieux_niveau_preuve_gradation.pdf
44. www.has-sante.fr/portail/upload/docs/application/forcedownload/2016-03/guide_methodologique_analyse_critique.pdf
45. www.has-sante.fr/portail/upload/docs/application/pdf/eval_interventions_ameliorer_pratiques_guide.pdf
46. www.has-sante.fr/portail/upload/docs/application/pdf/2011-11/guide_methodo_vf.pdf

These approaches are not considered as levels of evidence and must be supported by rigorous qualitative methodology if they are to be cited. Academic research in this area is being developed.

Example: An app/SD is used in a randomised controlled trial as part of a programme for monitoring and promoting physical activity in the elderly. The RCT results show a reduction in falls in the intervention group. The app/SD cites the publication in its references and mentions its role as a monitoring tool.

More information:

It is worth noting that Kumar (71) has suggested adapting assessment methodology for the publication of measurement accuracy or therapeutic efficacy. Tomlinson (72) has envisaged changes in mHealth assessment methodology over the coming years. Whittaker (36) proposes different methodological evaluation phases (from focus groups to impact studies) for assessing the quality of apps.

Bull (68) hopes that psychosocial and psychological approaches will be better evaluated.

Hussain (20) sets out the different currently published approaches to assessing an app.

▶ Description of intended use

Has the main intended use (aims or objectives) of the product been described in detail and can this be consulted by anyone?

Justification: This declaration is an important part of defining how the product will be used.

If the manufacturer's declared use is as an instrument, apparatus, appliance or software intended to be used in humans for the purposes of diagnosis, prevention, monitoring, treatment, or alleviation of a disease or injury (*Directive 93/42/EEC concerning medical devices*), it qualifies as a medical device. The manufacturer must contact the French National Agency for Medicines and Health Products Safety (ANSM) and comply with the applicable legal and regulatory requirements[47].

If the declared use is not appropriate, the intended use should be requalified.

Note that in some cases, the declared intended use may mask the intention to collect other types of data for other purposes (data collection, surveillance, geolocation, etc.). Particular attention should be given to detecting this bad practice.

Example: An app/SD that is intended to measure the user's average heart rate at rest in the context of regular physical activity should not be used as a reference for cardiac rehabilitation.

More information:

Wolf (73) evaluated apps/SDs that photograph melanomas. Use under medical supervision is more effective.

▶ Product language

Is the app/SD and its associated documentation available in the user's language?

Justification: When an app/SD is translated or when someone uses an app/SD that is not in their native language, there may be the risk that information is wrongly interpreted because of poor comprehension, "false friends" or an inaccurate translation resulting from the designers' translation process.

Example: A designer has used machine translation to translate the text in their app. A test reading by a user shows that the translation is not accurate. The product's designer implements a procedure to improve the translation of their app so that only languages which are actually supported are listed.

▶ List of terms/glossary

Does the app/SD have a glossary of terms used in the app?

Justification: A list of terms and their definitions helps to avoid any ambiguity or incorrect interpretation by users.

Example: An app includes links to a glossary for words that are considered "key" to understanding the text.

2.4.2 Subcategory: Standardisation

▶ Interoperability: semantic standards, standard terminologies

Are the semantics of information flow explicit and are the terminologies used between healthcare professionals and patients based on standards (e.g. HL7, SNOMED)?

Justification: Interoperability is an important issue for processing, disseminating and storing data. Use of a standard should be promoted and is the subject of a European initiative[48].

47. ansm.sante.fr/Produits-de-sante/Dispositifs-medicaux
48. ec.europa.eu/digital-single-market/en/interoperability-standardisation-connecting-ehealth-services

Example: The designer of a product implements an interoperability strategy from the product design stage onwards.

More information: Data interoperability (*EU eHealth interoperability framework*) is covered in the European Commission green paper on mobile health (74).

▶ Data precision and reproducibility

Is the precision (accuracy) of measurements compared to a gold standard and is data reproducibility documented and appropriate for the intended use of the product?

Justification: If measurements are collected, their metrological characteristics must be transparent so that their levels of precision and accuracy can be understood. Precision should be appropriate for the expected use of the product.

This is a critical category because the accuracy of data collected may vary between the products available on the market and their intended uses. Users should be aware of the precision and reproducibility of data measured for the intended use.

Example: A product measuring physical activity is calibrated against a gold standard and its level of precision (or margin of error) is stated by the manufacturer.

▶ Data granularity

Can the smallest level of data measured be justified by the intended use of the product (refreshing, sampling frequency, etc.)?

Justification: The raw signal collected may vary in precision depending on the settings and sensor capacities. In some situations, loss of data related to overly coarse granularity may result in incorrect interpretation.

Example: The accelerometer setting of a sensor used to track mobility is not adjusted to the height of short individuals. The product's designer implements a procedure to improve this measurement.

▶ Information loss (through aggregation, compression, etc.)

Are the methods of aggregation, data smoothing, producing curves or other processing documented and are they justified by the product's intended use?

Justification: Here, the potential risk of loss of information should be evaluated in relation to its use. The raw signal should be processed appropriately based on the intended use of the product. In some situations, loss of data associated with data smoothing may lead to incorrect interpretation.

Example: A smart device measures the force produced by a user. It gives erratic maximum force results because of excessive data smoothing. The product's designer implements a procedure to improve signal processing and thus improve the overall product.

▶ Measurement performance in the environment of use

Is measurement performance documented in the environment or context of use (contextual robustness) and is it justified by the intended use of the product?

Justification: A measurement taken in a real-life situation may differ from measurements taken in the laboratory.

The measurement of health or wellbeing data in the user's environment should be high quality.

Example: An activity tracker worn on the wrist of a user with extrapyramidal syndrome may provide inaccurate data due to the tremor at rest caused by the disease.

▶ Possibility of synching data

Is there an option to sync data across multiple devices? Has the user's prior consent been obtained?

Justification: mHealth can involve several types of device: smartphones, tablets, watches, etc. The manufacturer should offer the option of synching one user's data across multiple devices.

Example: Users can log in with an ID and password on their tablet at home or on their smartphone outside to monitor their physical activity.

2.4.3 Subcategory: Generated Content

Note that this section should overlap with the subcategories **standardisation** and **cybersecurity** (user authentication, app authentication, data integrity and authenticity, etc.).

▶ Relevance of data collected

Is the choice of data collected justified by the intended use of the product?

Justification: The manufacturer must be able to justify the information used by their product and avoid any slide into mass data collection or malicious use. Some products may offer a service and, while it is being used, collect data that are unrelated to the service offer (but that have commercial value, for example).

Example: External evaluators will check that the stated purpose matches the actual use.

▶ Minimisation of data collected

Is the choice of data collected compliant with the principle of data minimisation, which requires that only data necessary for the product's intended use are collected?

Is the information given to users accessible and transparent for all data collected?

Justification: The principle of minimisation must be followed and explained transparently to users so that they are objectively informed about how their data are used.

Example: An app conducting prospective research into different parameters of the user's quality of life describes the actual data collected and the timescale of collection.

▶ Number of interfaces/peripherals/applications

Is the number of interfaces/peripherals/applications that the app/SD communicates with appropriate for the device's resources and the intended use of the product? Is the information given to users accessible and transparent for all data collected?

Justification: The number of interfaces/peripherals/applications must be explained transparently to users so that they are objectively informed about how their data are used. The app/SD should use what is strictly necessary for the declared intended use to avoid abusive collection or use of data.

Example: A food tracking app uses the smartphone's camera and connected kitchen and bathroom scales. The user is informed of these connections to peripherals.

▶ Relevance of information in context

Is the content appropriate to the user's needs (useful, beneficial, etc.) in their current situation?

Justification: When content is "generated" during use, it must be appropriate and helpful to the user.

Example: An app for tracking physical activity generates advice or encouragement based on the user's activity level.

▶ Discussion forums

Is the discussion forum moderated and governed by guidelines that include terms and conditions and forum rules?

Justification: Moderation and guidelines are ways to improve the quality of discussion forums. They help to prevent the dissemination of incorrect or malicious information. Disagreeable comments should only be intentionally deleted by a moderator as indicated by the policy of use and the rules.

Example: In a health education app, the designer sets up a discussion forum on addiction in the health sphere. All comments are monitored by two moderators who approve the content provided by users.

▶ User support, hotline

Is there a hotline where users can request assistance if they have any questions about using the product (understanding its content and using its functions)? Are frequently asked questions documented and can they be consulted (FAQ page, etc.)?

A quality process for obtaining, addressing, monitoring and responding to user feedback may be documented, depending on the purpose of the app/SD.

Justification: User support for a product can improve the quality of use. This support may take different forms, depending on the product's aims and various factors relating to its use (data management, multilevel interface, etc.).

Example: A reminder app for taking medicines offers an FAQ on setting alerts and notifications.

2.4.4 Subcategory: Interpreted Content

▶ Algorithm types

Are the types of algorithm used stated, so that users know whether the app/SD uses "proprietary" algorithms and/or "open" algorithms or algorithms that use published calculations or scores?

Justification: Generated content may be interpreted by the manufacturer's own algorithm or by one that uses published equations and calculations. The type(s) of algorithm used should be transparent to the user.

Example: A laboratory reference value app for doctors calculates the therapeutic ranges that can be used. The references values come from an identified database and calculations are made using equations that are referenced in the app.

More information:

Albrecht (75) makes some suggestions for safety in the development of algorithms.

Bierbrier (76) lists the most common medical calculation apps and assesses the accuracy of the calculations. Six out of 14 apps were 100% accurate. The errors were not critical, but the calculations and functions of these apps should be evaluated.

Also concerning accuracy of calculations, Chyjek (77) evaluated apps that indicate pregnancy due dates. More than half provided inaccurate dates.

Huckvale (78) found errors in calculating blood glucose in more than half of apps (eight input issues and five output issues).

▶ Human interpretation of health content

If there is human (non-automatic) interpretation of health-related content (health data, scientific content, etc.), is this done by qualified healthcare professionals?

Justification: Interpreting scientific content or health data needs to involve physicians or healthcare professionals, depending on the case.

Examples: A wireless heart rate monitor collects physical activity data from a user. This information is sent to a physician/cardiologist for advice.

A journal club app offers a press review and an interpretation of data from the literature. External reviewers, who are healthcare professionals in the field, make sure that the interpretation is correct and there is no bias in the articles selected.

▶ Automated interpretation of health content

Are the algorithms for interpreting health-related content evaluated (health data, scientific content, etc.)? Are the testing plan and reports documented?

Justification: If scientific content or health data is interpreted automatically, the accuracy of the interpretation should be assessed. The credibility of algorithm testing is a key element that should be evaluated to ensure accuracy.

This criterion may need to be updated in the next few years, because the mHealth sector and the current level of technology is contributing to the development of algorithms.

Examples: A wireless heart rate monitor collects physical activity data from a user. Based on the results, the user is automatically assigned a training programme. External evaluators should assess the level of risk involved in interpretation by checking the reliability of tests used by the designer(s).

A multisearch engine for articles aims to rank the best articles available. External evaluators could carry out different targeted tests to compare the relevance of the results obtained or the testing plans used by the designer(s).

An automatic query is sent to scientific databases to target specific articles from a particular field.

2.5 Category: Technical Content

The technical content category (Table 5 on the next page) is mainly assessed by external evaluators.

The European Union hopes for the development of apps/SDs that users can trust (79).

2.5.1 Subcategory: Technical Design

The technical design subcategory also overlaps with the **cybersecurity** subcategory (safe use of third-party code, etc.).

▶ Device configuration and performance[49]

Are device configuration and performance documented and are they compatible with the product's intended use and main user?

Justification: Device performance may become an insurmountable issue if it does not match the expected standards for use of the product.

49. The term "device" means any hardware where the application runs (smartphone, PDA phone, tablet, etc.) or smart device.

Table 5. List of criteria related to products' technical content

SUBCATEGORY	TITLE	STANDARD REQUIRED/CRITICALITY LEVEL FOR APPS/SDS
		Low / Medium / High
Technical design	Device configuration and performance	R / R / R
	Software development methodology	D / D / R
	Update tracking	R / R / R
Data flow	Interface with electronic patient record[50]	D / D / D
	Backward compatibility	D / R / R
	Data import, export and reversibility	C / C / C
	Data model	D / D / D
	Data hosting arrangements	C / C / C
	Data hosting and backup procedure	C / C / C

D Desirable R Recommended C Compulsory

Device requirements can include:

- screen definition and size when reading images/videos[51];
- sound quality when recording or playing sound;
- metrological characteristics in terms of sensors and data collected;
- etc.

Example: An app is designed to take photos of melanomas so that patients can save them and show them to their dermatologist. This requires a suitable camera and accurate image processing.

▶ Software development methodology

Have quality control and frameworks for software development been implemented?

Justification: The software design methodology should be based on explicit methods and an explicit quality approach.

Example: Several software development methods are cited: agile, Scrum, Extreme Programming, UML, etc.

External evaluators should assess the credibility of the design.

50. An interface with an electronic patient record is not a legal requirement, but setting one up entails compliance with the provisions on data sharing and medical confidentiality.
51. www.knowtex.com/nav/prometee-un-living-lab-pour-faire-rimer-medecine-et-numerique_42225

▶ Update tracking

Is the version history documented, including changes made (developments and fixes)?

Justification: A list of versions and historical changes made should be kept up to date to chart the product's development. Quality in the development of an app requires transparency in its design and transparent update tracking.

Example: External evaluators may ask for a list of this history.

2.5.2 Subcategory: Data Flow

▶ Interface with electronic patient record

Does the app/SD have an interface with an electronic patient record? Does this interface comply with the legal and regulatory conditions that apply to data sharing?

Justification: Electronic patient records and their interface with the mHealth environment is an important subject. The situation with electronic patient records is developing and changes are likely; regulatory requirements on the subject should be adhered to.

Example: A connected scale sends the user's weight history to their electronic patient record.

▶ Backward compatibility

Is downward compatibility documented (the product's compatibility with previous versions)?

Justification: If a product has collected personal data or interacted with the user, continuity of data use should be guaranteed across different versions of the app/SD.

Example: A physical activity tracker guarantees users continuity of the data collected across product versions.

▶ Data import, export and reversibility

Are the functions for data import, export and reversibility (conversion to standard formats) documented?

Justification: If a product has collected personal data or interacted with the user, data import, export and conversion should be guaranteed.

Example: A connected scale allows data to be imported/exported in various compatible formats.

▶ Data model

Is the data model documented, describing how data are depicted and managed?

Justification: The term "data model" is used to explain how data are managed (databases, mathematical depictions, etc.).

Example: External evaluators may ask about the type of data model used to assess its suitability.

▶ Data hosting arrangements

Are the data hosting arrangements documented and do they meet legal and regulatory requirements?

Justification: There are regulatory requirements for how data is hosted (using an approved host when outsourcing the hosting of personal medical data; host security, etc.). In other unregulated contexts, the hosting arrangements must be transparent.

Example: External evaluators may ask about the hosting type and assess its risks.

▶ Data hosting and backup procedure

Is the backup procedure documented, including frequency, format, storage sites and recovery mechanisms, and does it comply with legal and regulatory requirements?

Justification: The backup procedure for data is a guarantee of security and must be maintained. In other unregulated contexts, the backup procedures must be transparent.

Example: The manufacturer informs users of the backup procedures used.

2.6 Category: Security/Reliability

The security/reliability category (Table 6, on the next page) mainly covers cybersecurity, information reliability and risks relating to personal data. Tools for evaluating these areas may take "threat and risk assessment" approaches. Depending on the situation, external evaluators may be needed.

Table 6. List of criteria related to product security and reliability

SUBCATEGORY	TITLE	STANDARD REQUIRED/CRITICALITY LEVEL FOR APPS/SDS
		Low / Medium / High
Cybersecurity	Threat analysis	C / C / C
	Security in development	C / C / C
	Security of cryptographic functions	C / C / C
	Code protection/verification methods	C / C / C
	Safe use of third-party code	C / C / C
	User/data authentication	C / C / C
	App/SD authentication	C / C / C
	Data integrity and authenticity	C / C / C
	Transfer/exchange of secure data	C / C / C
	Data sharing and access with other apps/SDs	C / C / C
	Secure data storage on the device	C / C / C
	Secure data storage on remote server(s)	C / C / C
	Remote service insecurity and faults	C / C / C
	Security maintenance	C / C / C
	User awareness, potential causes of confidentiality breach	R / R / R
	Security assessment	R / R / R
	Signalling and transparency concerning data breaches and security incidents	C / C / C

SUBCATEGORY	TITLE	STANDARD REQUIRED/CRITICALITY LEVEL FOR APPS/SDS		
		Low	Medium	High
Reliability	Reliability and maintainability of hardware (sensors) and software	D	R	R
	Infrastructure availability	D	D	R
	Technical support, hotline	D	R	R
	Materials quality, device safety	C	C	C
	Media file optimisation	D	D	R
	Contraindications, potential risks, limitations of use	R	R	R
	Availability level	D	D	R
	Preventive maintenance	D	D	R
	Functioning with other apps/SDs	R	R	R
Confidentiality	Recipient of data collected, personal data confidentiality, and consent for transmission to third parties	R	R	R
	Pseudonymisation of data	R	R	R
	Anonymisation of data	C	C	C
	Deletion time limits and time to implementation	C	C	C
	Insurance and legal cover for data loss	D	D	D

D Desirable R Recommended C Compulsory

Note that various search engines[52,53,54] locate and index available smart devices on the internet. Poorly protected devices may thus be identified and used by malicious individuals.

52. censys.io
53. www.shodan.io
54. thingful.net

2.6.1 Subcategory: Cybersecurity

Satisfaction with the security standards of a product depends first and foremost on the use of "security functions" (encryption, authentication, integrity verification, etc.), which are detailed below in this document.

It also requires compliance with design principles and the use of methods intended limit the risk of introducing faults during the app/SD's development and life cycle.

The legal situation on data storage or aspects of cybersecurity is likely to evolve regularly. Developers should be aware of these changes to remain compliant with the regulations.

▶ Threat analysis

Has a threat analysis been performed for the app/SD? Is data protection taken into account by design and by default when the app/SD is created?

Justification: A threat analysis should be performed on the app/SD before it is used. This threat analysis should be able to identify what sensitive information is handled by the app/SD, and which security functions can counter threats that may jeopardise the confidentiality, integrity and availability of sensitive information. The threat analysis should also be able to set security at the "right level".

The concepts of *protection by design* and *protection by default* refer to protective measures that are included even in the specifications of a software product and are intended to counter an identified threat.

Example: External evaluators may ask whether a threat analysis has been performed (for example, the EBIOS method: Expression of needs and identification of security objectives[55]) External evaluators may ask whether the design of the app/SD includes built-in authentication, pseudonymisation, and secure data transfer and storage functions.

More information:

Martinez-Perez (80) offers some guidelines on data security following a literature analysis.

▶ Security in development

Are the methods and tools used at different stages of the app/SD's development cycle to anticipate and detect faults documented?

Justification: Faults may accidentally be introduced during development, which must therefore be based on safe design tools and methods. Security in software development is one of the measures taken to improve the overall quality of an mHealth product.

Example: External evaluators may ask about the design methods and tools used by the developers.

▶ Security of cryptographic functions

Have the developers prioritised the use of tried and tested cryptographic services and primitives (for example, those offered by the mobile device's operating system) over redeveloping analogue functions?

Justification: Robust and reputable systems are needed in this sector. Developing these functions is particularly difficult and requires expert skill.

Example: External evaluators may ask about the type of cryptographic service.

▶ Code protection/verification methods

Is code integrity subject to regular protection and verification procedures, to prevent the app/SD from being diverted from its normal purpose and used, for example, as a tool for spying on the device owner or to prevent malicious changes to code and/or data integrity?

Justification: Protective measures for integrity are just as essential as those for data confidentiality.

Example: External evaluators may ask about protection methodology.

▶ Safe use of third-party code

Does the app/SD use third-party code to operate? Has this third-party code been reviewed to assess its security and robustness?

Justification: Designers that use third-party code take responsibility for its use in their products. It is their duty to maintain reliability and safety of use, and to ensure that no marketing data are collected without users' knowledge.

Example: External evaluators may assess the processes for managing third-party code. Evaluators could also evaluate the appropriateness of third-party apps/SDs in light of the product's purpose.

55. www.ssi.gouv.fr/guide/ebios-2010-expression-des-besoins-et-identification-des-objectifs-de-securite

▶ User/data authentication

Are the mechanisms for authenticating users with the app/SD or remote services documented? Are they compatible with user anonymity standards (for example, using connection pseudonyms that are unrelated to the user's identity)?

Justification: If data are exchanged between the app/SD and remote services, the user authentication mechanisms must be specified.

Example: External evaluators assess the risks of user authentication based on documents provided by the manufacturer.

▶ App/SD authentication

Does the app/SD authenticate the remote services with which it exchanges data? Is this authentication reciprocal? How is authentication carried out? If a server cannot be authenticated, does the app/SD break off communication and warn the user? Is there a remote certification mechanism?

Justification: Authentication of the app/SD with the infrastructure must be reciprocal. This reciprocal authentication should allow the app/SD to check the identity of remote services with which it exchanges data, and allow these services to check that the data they receive does come from a legitimate app or smart device.

NB: A distinction should be made between user authentication with the app/SD, and authentication of the app/SD with remote services.

Where applicable, remote services can supplement this app/SD authentication with a procedure known as certification, where access to the services is either blocked or authorised depending on the app/SD's "status" (status is a measure of the app/SD's integrity).

Example: External evaluators assess the risks of authenticating a product based on documents provided by the manufacturer.

▶ Data integrity and authenticity

Are the mechanisms for verifying the integrity and authenticity of data exchanged between the app/SD and remote services documented?

Justification: The mechanisms for verifying data integrity and authenticity should allow components of the app/SD (local and remote) to detect any alteration in the data exchanged and to provide proof of their origin.

Example: External evaluators assess the risks relating to the integrity of a product's data based on documents provided by the manufacturer.

▶ Transfer/exchange of secure data

Is the confidentiality and integrity of data sent to remote servers guaranteed throughout transfer? Is this protection provided through a robust encryption protocol using state-of-the-art cipher suites (such as TLS)? Is this protocol used independently of the supporting network (Wi-Fi, mobile data connection, etc.)?

Is there guaranteed encryption of additional data from the confidential channel established with any remote servers?

Justification: Designers must guarantee users secure data exchange. They must also meet their obligations as regards transferring data outside the European Union.

Example: External evaluators may ask who holds the keys and how they are protected. Is there a recovery mechanism?

▶ Data sharing and access with other apps/SDs

Does the app/SD access data or resources generated by third-party apps/SDs? Can users control access to these data and resources at their discretion? Does the app/SD intend to share the data it manages with other apps/SDs? What security measures are in place to prevent illegitimate access to these data (for example, via a malicious app)?

Justification: Access by an app to external data and resources must comply with the legislation on information sharing. In particular, the app must minimise the exposure of the data it handles as far as possible.

Example: A settings screen allows users to send their physical activity data to various selectable apps/SDs.

▶ Secure data storage on the device

Is there guaranteed encryption of data stored on the device, in addition to the general encryption measures offered by the operating system?

Justification: Designers should guarantee the security of data on the device and on the server.

Example: External evaluators may ask who holds the keys and how they are protected. Is there a recovery mechanism?

▶ Secure data storage on remote server(s)

Is there guaranteed encryption of data stored on the remote server(s), in addition to the general encryption measures offered by the operating system?

Justification: Designers should guarantee the security of data on the remote server(s).

Example: External evaluators may ask who holds the keys and how they are protected. Is there a recovery mechanism?

NB: See also the regulatory requirements concerning approved health data hosts (HDS) when the app/SD requires it.

▶ Remote service insecurity and faults

Are there satisfactory standards for security, integrity and, where applicable, the availability of remote services that the app/SD interacts with? What methods are used?

Justification: Security incidents affecting an infrastructure are potentially more serious than an isolated incident on a patient's device, particularly in terms of data theft. Protection of remote services is therefore as essential, if not more so, as protecting apps/SDs.

Example: External evaluators may assess the security risks relating to remote services.

More information about remote web service-related risks: The OWASP website lists the 10 most critical vulnerabilities (81):

- injection flaws;
- broken authentication and sessions management;
- cross-site scripting (XSS);
- insecure direct object references;
- security misconfiguration (servers, etc.);
- sensitive data exposure;
- missing function level access control;
- cross-site request forgery (CSRF);
- using components with known vulnerabilities;
- unvalidated redirects and forwards.

NB: The concept of "remote services" is not limited to web services alone, although these predominate in the app/SD sector. The information above should not be considered an exhaustive list of remote service-related threats.

▶ Security maintenance

Does the developer/designer ensure that identified faults on the app/SD are tracked and corrected?

Does this tracking also apply to third-party software (such as libraries) used by the app/SD?

Justification: Designers must guarantee that the security of apps/SDs and remote services is maintained.

Example: External evaluators may assess risks relating to the monitoring of product security.

▶ User awareness, potential causes of confidentiality breach

Does the app/SD make users more aware of good security practice?

Justification: The aim here is to limit the dissemination of personal data during a session on a smartphone/tablet (through a malicious reset) or during an attack that seeks to impersonate the user to access the authentic infrastructure (such as a phishing attack).

"General" advice on keeping one's smartphone or tablet secure should be accessible (activating system encryption, activating locking, keeping the system up-to-date, etc.).

Example: An app sends a notification about locking the smartphone to protect its content against loss or theft.

When changing their smartphone/tablet, users are made aware of good practice for properly deleting personal data from their old device.

It is recommended to read the **21 ANSSI guidelines** on securing smartphones[56], good information technology practice[57], security recommendations for passwords[58] or security recommendations for Wi-Fi networks[59].

▶ Security assessment

Has the robustness of security functions been evaluated and has the app/SD been audited to check whether the level of security is appropriate for the product?

Justification: Risk analysis can be carried out using different methodological approaches and allows the required security standard to be determined.

Example: External evaluators may ask how this audit was conducted and whether it was performed independently.

▶ Signalling and transparency concerning data breaches and security incidents

Is there a signalling and transparency procedure for security incidents?

Justification: In the event of a data breach and/or security incident, the app publisher or smart device designer must commit to transparency with the competent authorities (health authorities, ANSSI CERT-FR, CNIL, legal authorities where applicable) and with its users.

Example: An app sends a notification about updating the app following an identified security flaw.

More information:

- ISO 27001 Information Security Management[60];
- OWASP IoT Framework Assessment[61];
- ENISA guidelines[62]:
  - Identify and protect sensitive data on the mobile device (reducing risks of data theft or loss);
  - Handle password credentials securely on the device (risks: spyware, surveillance, financial malware using passwords for other purposes);
  - Ensure sensitive data is protected in transit (risks: network spoofing attack on the many networks used by smartphones);
  - Implement user authentication and authorisation and session management correctly;
  - Keep the backend APIs (services) and the platform (server) secure (risks: attacks on backend systems);
  - Secure data integration with third-party services and applications (risks: data leakage);
  - Pay specific attention to the collection and storage of consent for the collection and use of users' data (risks: unintentional disclosure of personal information);
  - Implement controls to prevent unauthorised access to paid-for resources (wallet, SMS, phone calls, etc.) (risks: abuse of usage/vulnerabilities of paid-for resources);
  - Ensure secure distribution/provisioning of mobile applications (mitigating all risks described in the top 10);
  - Carefully check any runtime interpretation of code for errors;
- Top 10 risks (ENISA)[63]:
  - data leakage following loss or theft of device (high risk);
  - unintentional data disclosure by the user (high risk);
  - improper decommissioning, allowing access to an attacker (high risk);
  - phishing (moderate risk);
  - spyware (moderate risk);
  - network spoofing attacks (moderate risk);
  - surveillance (third-party software takes over the camera, screen sharing, etc.) (moderate risk);
  - diallerware attacks (using premium SMS services or numbers) (moderate risk);
  - financial malware (intercepting or subverting bank transactions, etc.) (moderate risk);
  - network congestion (low risk).

56. www.ssi.gouv.fr/entreprise/guide/recommandations-de-securite-relatives-aux-ordiphones
57. www.ssi.gouv.fr/guide/guide-des-bonnes-pratiques-de-linformatique
58. www.ssi.gouv.fr/uploads/IMG/pdf/NP_MDP_NoteTech.pdf
59. www.ssi.gouv.fr/uploads/IMG/pdf/NP_WIFI_NoteTech.pdf
60. www.iso.org/iso/fr/home/standards/management-standards/iso27001.htm
61. www.owasp.org/index.php/IoT_Framework_Assessment
62. www.enisa.europa.eu/media/enisa-en-francais
63. www.enisa.europa.eu/activities/Resilience-and-CIIP/critical-applications/smartphone-security-1/top-ten-risks (accessed 25/02/2016)

2.6.2 Subcategory: Reliability

As regards the reliability of the product's generated or interpreted content, see the **content** category.

▶ Reliability and maintainability of hardware (sensors) and software

Are failure rates, measurement error rates, and hardware risks of all types evaluated and documented? Are recurrent bugs and security bugs in the software documented? Can the terms and conditions or use-based warnings be consulted by anyone?

Justification: Monitoring the product's reliability is an important step to consider during the design process. Monitoring procedures should be documented.

Example: External evaluators may ask how monitoring takes place to assess its credibility and effectiveness.

▶ Infrastructure availability

Are there documented measures to ensure the availability of the app/SD's support infrastructure?

Justification: The app/SD's support infrastructure and its availability are quality and credibility factors in its maintenance.

Example: External evaluators may ask how the support infrastructure is organised.

▶ Technical support, hotline

Is there a *hotline* where users and resource persons can submit a request for technical assistance (bugs, workstation setup, operating system, etc.)? Are common problems documented and can they be consulted (FAQs, etc.)?

Justification: Technical assistance in an appropriate format should be available to users to help them resolve any problems.

Example: External evaluators may ask how the hotline works or how the FAQ were compiled and what the most common problems are. Any "debug" process used by the developers can be documented.

▶ Materials quality, device safety

Is the identification process for risks relating to the materials used (allergies, physical risks, etc.) and device safety (risk of burns, etc.) documented and evaluated by independent, qualified healthcare professionals?

Justification: Smart devices must not physically harm the user.

Example: A smart device has hypoallergenic wristbands.

▶ Media file optimisation

Are the procedures chosen for optimising media files (images and videos) documented and are they justified by the intended use of the product?

Justification: This criterion is about ensuring that the risk of data loss through compression and any connection, display and transmission delays (etc.) are acceptable. Media files are optimised for definition and size without increasing the risk of loss of quality for the user, and this is tested.

Example: The time taken to display a video of an interview is too long for an informative health app aimed at the general public. The product's designer implements a file optimisation procedure.

▶ Contraindications, potential risks, limitations of use

Are contraindications, potential risks and limitations of use evaluated and documented by a competent group? Is this information accessible for users to consult?

Justification: An app/SD may have limitations in terms of use or reliability. Users should be given transparent information.

Example: An optical sensor on a heart rate monitor may be unreliable depending on skin pigmentation (tattoos, skin colour, etc.). Users are informed of this limitation.

▶ Availability level

Is the product's availability documented and appropriate for its intended use (for example seven days a week and 24 hours a day, or a narrower timeframe such as 9am to 6pm on working days)?

Justification: The intended use of some products requires permanent connection with the remote web network.

Example: An activity tracker for athletes who are returning to sport after an injury collects information on pacing and rest phases. This requires continuous storage and/or transmission of the data collected.

▶ Preventive maintenance

Are failure detection systems and alerts in place to prevent faults that could cause inconvenience or harm to the user (low battery alerts, etc.)?

Justification: Users should be informed of how well the app/SD is functioning and notified of updates or the need to charge the battery when data is collected continuously or for a specific use.

Example: A smart device sounds an alert or vibrates to indicate that its battery is low.

More information:

ISO/IEC/IEEE 15288:2015: Systems and software engineering – System life cycle processes.

▶ Functioning with other apps/SDs

Are compatibility and conflicts between apps/SDs evaluated and monitored?

Justification: Compatibility or conflicts with other apps/SDs are monitored to collect details of problems encountered by users and to inform users of any incompatibilities.

Example: A user has a problem with an app/SD conflicting with his or her smartphone camera. The app/SD designer is alerted of the incompatibility. Users receive a notification to advise them of this until a fix can be applied.

2.6.3 Subcategory: Confidentiality

The French Data Protection Act[64] sets out the principles that must be respected during collection, processing and storage of personal data, particularly as regards confidentiality.

CNIL provides compendia of good practice to address the risks that personal data processing can have on the civil liberties and private life of data subjects[65].

The General Data Protection Regulation (GDPR) was adopted in April 2016[66] and should be implemented in France by 6 May 2018[67]. It is important to keep abreast of these developments.

In 2013, Sunyaev (82) carried out a study showing that only 30.5% of the most commonly used mHealth apps have a confidentiality policy.

The French Association of Data Protection Correspondents (AFCDP) has produced a summary of work on the connected *quantified self* and data protection[68].

▶ Recipient of data collected, personal data confidentiality, and consent for transmission to third parties

If the data collected is transmitted to third parties (complying with legal and regulatory requirements), is this explicitly documented (recipients, etc.)?

Can this information be consulted separately from the general terms and conditions?

Can users change their consent?

Justification: Any transmission to a third party requires the user's prior consent, as specified by law.

Example: A setting can be accessed to change consent for transmission to third parties.

▶ Pseudonymisation of data

Is the pseudonymisation process documented and can it be consulted?

Justification: The process of pseudonymising personal data is an important issue in mHealth.

Example: External evaluators may ask how pseudonymisation is done. They may ask how indirect means of lifting anonymity are controlled. For example, does the app/SD have unique identifiers for the device where it is installed, and are these unique identifiers linked in any way with the user's identity (phone number, etc.)?

▶ Anonymisation of data

If individuals' data, particularly health data, are sent for statistical processing, are they anonymised?

Is the anonymisation process documented and can it be consulted?

64. Act no. 78-17 of 6 January 1978 on information technology, data files and civil liberties.
65. www.cnil.fr/fr/PIA-privacy-impact-assessment
66. eur-lex.europa.eu/legal-content/FR/TXT/HTML/?uri=CELEX:32016R0679&from=EN
67. ec.europa.eu/justice/data-protection
68. esante.gouv.fr/sites/default/files/asset/document/201502_synthese_qs_v10.3_finale.pdf

Justification: Anonymising data is obligatory before it is sent to any third party for statistical processing.

Example: External evaluators may ask how anonymisation is done.

More information:

Big data and governance discussed in the European Commission green paper (74).

Personal data good practice from the Council of Canadian Academies (83).

Background and guidelines from AFNOR (84).

CNIL documentation (34).

▶ Deletion time limits and time to implementation

Are the durations and time limits of data storage or deletion documented and can they be consulted by users?

Justification: Users must be made aware if health data is stored on servers or any other medium. The storage time needed to achieve objectives must be stated and not exceeded, unless another legal obligation requires a longer storage period.

Example: The designer's information page describes the data storage policy. External evaluators may ask for documentation on this subject.

▶ Insurance and legal cover for data loss

Is insurance and legal cover provided to compensate users for any loss of data collected? Is a certificate available for consultation?

Justification: Legal or insurance cover protects the liability of the designer.

Example: External evaluators may ask for documentation on this subject.

2.7 Category: Usability/Use

The usability/use category (Table 7) mainly covers how people will be able to use the app/SD. This category covers areas of assessment that can be subjective or difficult to evaluate. However, it is a field that impacts on the regular and effective use of the product.

Table 7. List of criteria related to product use

SUBCATEGORY	TITLE	STANDARD REQUIRED/CRITICALITY LEVEL FOR APPS/SDS		
		Low	Medium	High
Usability/design	Ergonomics	R	R	R
	Installation and setup process	D	R	R
	User help/instructions	R	R	R
	User-friendliness and intuitiveness	R	R	R
	Text and image readability	R	R	R
	User abilities	D	R	R
	Accessibility of content for disabled users	R	R	R

D Desirable R Recommended

SUBCATEGORY	TITLE	STANDARD REQUIRED/ CRITICALITY LEVEL FOR APPS/SDS
		Low / Medium / High
Usability/design	Ease of use	R / R / R
	Error prevention	D / R / R
	Use cases, business scenarios	D / R / R
	Flexibility/customisation	D / R / R
	Response times, display time	R / R / R
Acceptability	Evaluation by external healthcare professionals	R / R / R
	Evaluation by the main target population	R / R / R
	Satisfaction survey	R / R / R
	Usability (user adherence over time, regularity of use)	D / R / R
	User engagement (taking an active role)	R / R / R
	Dosage and use (measurement of adherence)	D / R / R
Integration/import	Open infrastructure	D / D / D
	Search capacity	D / D / R
	Capacity to search for a patient	D / D / R
	Option to print summaries (selection)	R / R / R
	Social elements (private life and social networks)	D / D / D

D Desirable R Recommended

2.7.1 Subcategory: Usability/Design

▶ Ergonomics

Has the interface been designed based on an ergonomic approach (existing ISO standards, AFNOR standards, etc.)? Is this process documented?

Justification: Ergonomics are an implementation factor for the user.

Example: External evaluators may ask for documentation on this subject.

More information:

French State Internet Charter[69]: This ergonomic charter for public-sector websites aims to define a set of common ergonomic rules for the interfaces of public-sector websites. It complies with World Wide Web Consortium (W3C) standards and the principles of the French general interoperability (RGI), accessibility (RGAA) and security (RGS) guidelines.

Cruz Zapata (85) offers some guidelines on interface for developers.

▶ Installation and setup process

Has the installation and setup process been tested on the main OS, web browsers and platforms offered in the environment of use? Is this procedure documented?

Justification: The designer should carry out test phases to ensure a high-quality user experience.

Example: External evaluators may ask for documentation on this subject.

▶ User help/instructions

Can users access a help system for the product (context-sensitive help, online help, user manual, tutorials, training software, e-learning, etc.)? Does this system promote the user's learning capacities (learnability)?

Justification: The level of training support provided for users by the designer can optimise use of the product.

Example: When an app/SD is launched, help screens are available to guide users through their first use.

▶ User-friendliness and intuitiveness

Have the user-friendliness and intuitiveness of the interface and navigation been tested with different user profiles? Are the testing plan and report documented?

Justification: Designers look for user profiles with different learning styles or profiles based on specific criteria related to the target users so the app/SD can be adapted.

Example: External evaluators may ask for documentation on this subject.

▶ Text and image readability

Has the readability of the different media used (text, images, videos) been tested? Are the testing plan and report documented? Does the interface or OS allow the app/SD's readability to be changed (different text size, font, etc.)?

Justification: Readability by users with different abilities is a factor in the product's accessibility.

Example: Users can access a settings screen to change the font size and make videos full screen.

▶ User abilities

Have different user profiles been identified based on intended usage of the product and possible difficulties with interface readability or user ability? Are the abilities required of a novice, experienced or expert user accessible to all?

Justification: Different types of user may navigate the product interface differently.

Example: Colour-blind users and elderly people were identified for work on the use of colour and contrast in the interface of an informative app on pulmonary rehabilitation.

More information:

Arnhold (86) evaluated the interface of apps for elderly people with diabetes. Watkins (87) conducted a systematic review on older people and health literacy.

Monkman (88) evaluates risk based on the interface and the user's health literacy.

69. references.modernisation.gouv.fr/sites/default/files/Charte_ergonomique_v2.0_2.pdf

▶ Accessibility of content for disabled users

Have accessibility guidelines for people with disabilities been followed?

Justification: Designers should ensure their products are accessible.

Example: The designer sets up a specific user test for disabled users.

More information:

French State Internet Charter[70]: This ergonomic charter for public-sector websites aims to define a set of common ergonomic rules for the interfaces of public-sector websites. It complies with World Wide Web Consortium (W3C) standards and the principles of the French general interoperability (RGI), accessibility (RGAA) and security (RGS) guidelines.

▶ Ease of use

Is there a simplification process in place? Is this process documented?

Justification: User feedback should allow designers to make their products simpler to use.

Example: Some menu items were deleted after incorrect or non-use of these items in a medicines database app for physicians. Users then needed less time to find the information they were seeking.

▶ Error prevention

Is there an appropriate alert system during critical user decisions, to prevent potential misuse?

Justification: Some interactions may lead to user error. Designers should ensure that users are alerted to this.

Example: A body mass index calculator displays an alert concerning the unit of measurement for height, or has a drop-down menu to limit input errors.

▶ Use cases, business scenarios

Do the use cases (or business scenarios) cover the product's main functions and lead to a better understanding of different uses of the app/SD (scenarios)? Are these use cases documented and tested?

Justification: The navigation and pathways taken by users in an app may be very different. This is also the case for smart device settings. Identifying different scenarios helps to prevent potential misuse and improve navigation within the app.

Example: An app for managing medicines use allows users to schedule doses of medication that repeat at set times over a fixed period. Some users are not aware of this function and are scheduling each day separately, a week in advance. Identifying this scenario would allow specific help to be offered.

More information:

Caburnay (89) reviews the design of diabetes apps.

Collins (90) has developed tools for evaluating the quality of health questionnaires for patients using apps health literacy[71]).

Various tools are available to evaluate patient comprehension.

▶ Flexibility/customisation

Has adaptation to users' abilities, needs or requirements been considered?

Justification: mHealth has allowed apps/SDs to be developed for "niche" groups of professionals or patients. It is possible to offer several different specific versions that correspond to users' needs.

Examples: A platform for sharing documents between patients and professionals allows different access levels and different information views based on users' rights.

A specific control panel activates a simplified or advanced menu, depending on the user's needs.

▶ Response times, display time

Have response times and display time been tested and adapted based on the intended use of the product? Is there a documented testing plan, including a definition of the test environment, and testing report?

Justification: Fluidity of navigation is a factor that affects user loyalty.

Example: External evaluators may test response times on the testbed.

More information:

70. references.modernisation.gouv.fr/sites/default/files/Charte_ergonomique_v2.0_2.pdf
71. health.gov/healthliteracyonline/2010/Web_Guide_Health_Lit_Online.pdf

Georgsson (91) carried out an assessment of tasks (following standard ISO 9241-11). This showed that more complex tasks result in more errors. Five to eight users can find 80-85% of interface problems. Task completion was graded using three categories: without help, with help, and failed despite help.

2.7.2 Subcategory: Acceptability

▶ Evaluation by external healthcare professionals

Has the app/SD been evaluated by independent healthcare professionals or healthcare professionals' organisations?

Justification: As part of quality management, an external evaluation should be carried out.

Examples: A group of healthcare professionals set up an app/SD for collecting patient data to obtain statistics on patient management and follow-up. They publish an article on the subject in a peer-reviewed journal.

A professional association evaluates a dozen apps/SDs concerning a specific field in their sector of activity. The results are distributed to members and the owners of the apps/SDs cite this evaluation in their presentation.

▶ Evaluation by the main target population

Is the app/SD evaluated by independent users or user groups?

Justification: Testing by target users under real-life conditions is a way to obtain feedback on the product's quality.

Example: An app/SD that allows angles to be measured on videos does not save these measurements. This user feedback allows the designer to make changes.

▶ Satisfaction survey

Is user satisfaction evaluated? Are the results of the evaluation documented and can they be consulted by anyone?

Justification: Transparency of user feedback is an information standard. It can be manipulated by "fake" users who are paid to give positive views.

Example: External evaluators may analyse the data and assess their reliability.

▶ Usability (user adherence over time, regularity of use)

Has regular use of the app/SD been evaluated, if this is one of the product's objectives?

Justification: Currently, some apps/SDs have a limited lifetime. Designers should monitor usage/visit statistics.

Example: A designer publishes their use rate to highlight their popularity and user loyalty.

▶ User engagement (taking an active role)

For an app/SD that aims to help users take a more active role in their health, are users engaged and is this evaluated? Is the process transparent and documented?

Justification: Self-tracking (the *quantified self*) is a fast-growing objective in mHealth. Designers should highlight the measures taken to encourage autonomy in self-tracking.

Example: A connected scale encourages patients to monitor various parameters, measured over several weeks, to gradually adapt their behaviours and lifestyle.

▶ Dosage and use (measurement of adherence)

Does the app/SD improve treatment adherence, if this is one of the product's objectives? Is this process documented?

Justification: Users may receive various types of reminder to improve their treatment adherence.

Example: SMS and mobile phone notifications help patients to take their treatment correctly.

More information:

Hall (92) has shown that SMS have a strong impact in various health issues.

Hamine (47) has shown that mHealth has a real impact on adherence in chronic diseases.

2.7.3 Subcategory: Integration/Import

▶ Open infrastructure

Can users manually enter data in the app/SD?

Justification: Some clinicians wish to add comments to certain data collected from a patient and some situations (loss of connection, user's internet down for several days, etc.) require data to be added to the app/SD.

Example: A user's activity tracker does not work for several days. The user copies data recorded for days with similar activity levels to the missing days in their tracking calendar.

▶ Search capacity

Does the user have access to an information search engine or a data search system where relevant?

Justification: Apps/SDs that use multiple information databases or include collected data should allow users to search via a search engine.

Example: An app/SD that compiles good practice guidelines allows specific searches.

▶ Capacity to search for a patient

If the patient consents, can the healthcare professional search for one or more patients?

Justification: Some healthcare professionals store medical information in a practice management app or other app. A search engine allows the document required to be found more quickly.

Example: The laboratory test results for a patient are saved in a database and may be found via a specific query.

▶ Option to print summaries (selection)

Can selected data be retrieved and printed in summary form?

Justification: Retrieving specific data allows users to keep a hard copy of article summary details, the result of a measure taken, a workout completed or a data compilation.

Example: A clinician collects specific articles about specific evaluation methods using a medical information app.

▶ Social elements (private life and social networks)

Is there a proven benefit to sending data to social networks? When data is transferred to social networks, does this comply with the law and regulations (explicit user consent, right to private life, etc.)?

Justification: Social networks are used, among other reasons, to strengthen support or develop a competitive factor when following the advice of a clinician or changing a behaviour. If this initiative is offered, it must have proven benefit.

Example: A "mood diary" app used by patients with depression allows them to share their mood on social networks with a group of friends. Clinical references on the benefit of this approach are available for consultation by anyone.

This function must comply with the law and regulations as well as with any medical opinion on the benefit of sharing this information.

3. Implementation of Good Practice Guidelines

Various theories of assessment and objective-based approaches have been published on the subject. Khoja (93) describes different phases in the life cycle of an app and the evaluation processes that could follow on from each of these phases.

For developers, there are also standardisation documents (such as ISO/IEC 90003 Software engineering – Guidelines for the application of ISO 9001:2008 to computer software, or IEC/FDIS 82304-1 Health software – Part 1: General requirements for product safety) which provide standards for different fields concerned by mHealth. These allow product developers to become certified.

In addition, there are guidelines such as PAS 277:2015 Health and wellness apps – Quality criteria across the life cycle – Code of practice, developed by the British Standards Institute (94), which aims to provide recommendations for developers.

Lobelo (95) proposes a framework for what he calls the *Wild Wild West*, as regards mobile health, wellbeing and physical activity.

Online stores also provide recommendations[72] to help developers get their products accepted for sale[73].

3.1 Possible Different Uses of the HAS Good Practice Guidelines

The HAS good practice guidelines may be used and adapted by a number of actors in the sector:

- developers, who could look for principles to integrate into their project(s);
- external evaluators, who could focus on what documentation to request;
- professional organisations, who could create summary tables (benchmarking) or graphics (radar charts) on specific apps/SDs using the criteria in the guidelines.

Each of the five categories in the guidelines can therefore be evaluated specifically or summaries can be produced to compare evaluations of different apps/SDs in the same field (with the same main objective and main user).

The “compulsory” criteria can be used to perform an initial analysis of an app/SD. If these are not met, the evaluation is not continued.

For some criteria relating to specific apps/SDs (particularly data flow), risk analysis or threat analysis methods should be used, as suggested for these criteria.

The interface from the user’s perspective (human-machine interface – HMI) can undergo an additional evaluation using standard scales such as the 10-question System Usability Scale[74] by Brooke (96) or the 21-question Quality of Experience (QoE) approach by Martinez-Perez (97).

The HAS good practice guidelines may be used as a reference when producing various deliverables:

- register;
- label;
- score;
- peer review;
- testbed;
- benchmark;

or when developing different approaches based on the evaluator’s objectives:

- objective/category-based approach (information quality, design process, security, etc.);
- segmentation-based approach (specific diseases, etc.);
- target-based approach (patients, students, healthcare professionals, designers/specific use);
- etc.

To identify how the guidelines are employed, their use could be monitored.

72. developer.apple.com/app-store/review/guidelines/#physical-harm
73. www.fiercehealthcare.com/mobile/apple-debuts-app-review-guidelines-quest-to-boost-quality
74. www.usability.gov/how-to-and-tools/methods/system-usability-scale.html

Appendix 1. Mobile App Rating Scale (MARS) (98, 99)

Available at: mhealth.jmir.org/article/downloadSuppFile/3422/14733

From 349 items assembled following a literature review, the scale has been reduced to 23 items graded from 1 to 5 in four objective categories and one subjective category.

Inter-rater concordance: ICC=0.79 and internal consistency: alpha=0.90

Section A – Engagement – fun, interesting, customisable, interactive (e.g. sends alerts, messages, reminders, feedback, enables sharing), well-targeted to audience.

Score out of 25 points

1. **Entertainment:** Is the app fun/entertaining to use? Does it use any strategies to increase engagement through entertainment (e.g. through gamification?) (5 multiple-choice answers graded 1 to 5 with descriptions.)
2. **Interest:** Is the app interesting to use? Does it use any strategies to increase engagement by presenting its content in an interesting way? (5 multiple-choice answers graded 1 to 5 with descriptions.)
3. **Customisation:** Does it provide/retain all necessary settings/preferences for apps features (e.g. sound, content, notifications, etc.)? (5 multiple-choice answers graded 1 to 5 with descriptions.)
4. **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. (5 multiple-choice answers graded 1 to 5 with descriptions.)
5. **Target group:** Is the app content (visual information, language, design) appropriate for your target audience? (5 multiple-choice answers graded 1 to 5 with descriptions.)

Section B – Functionality – app functioning, easy to learn, navigation, flow logic, and gestural design of app

Score out of 20 points

6. **Performance:** How accurately/fast do the app features (functions) and components (buttons/menus) work? (5 multiple-choice answers graded 1 to 5 with descriptions.)
7. **Ease of use:** How easy is it to learn how to use the app; how clear are the menu labels/icons and instructions? (5 multiple-choice answers graded 1 to 5 with descriptions.)
8. **Navigation:** Is moving between screens logical/accurate/appropriate/uninterrupted; are all necessary screen links present? (5 multiple-choice answers graded 1 to 5 with descriptions.)
9. **Gestural design:** Are interactions (taps/swipes/pinches/scrolls) consistent and intuitive across all components/screens? (5 multiple-choice answers graded 1 to 5 with descriptions.)

Section C – Aesthetics – graphic design, overall visual appeal, colour scheme, and stylistic consistency

Score out of 15 points

10. **Layout:** Is arrangement and size of buttons/icons/menus/content on the screen appropriate or zoomable if needed? (5 multiple-choice answers graded 1 to 5 with descriptions.)
11. **Graphics:** How high is the quality/resolution of graphics used for buttons/icons/menus/content? (5 multiple-choice answers graded 1 to 5 with descriptions.)
12. **Visual appeal:** How good does the app look? (5 multiple-choice answers graded 1 to 5 with descriptions.)

Section D – Information – Contains high quality information (e.g. text, feedback, measures, references) from a credible source. Select N/A if the app component is irrelevant.

Score out of 35 points

13. **Accuracy of app description (in app store):** Does app contain what is described? (5 multiple-choice answers graded 1 to 5 with descriptions.)
14. **Goals:** Does app have specific, measurable and achievable goals (specified in app store description or within the app itself)? (5 multiple-choice answers graded 1 to 5 with descriptions.)

15. **Quality of information:** Is app content correct, well written, and relevant to the goal/topic of the app? (5 multiple-choice answers graded 1 to 5 with descriptions.)
16. **Quantity of information:** Is the extent coverage within the scope of the app; and comprehensive but concise? (5 multiple-choice answers graded 1 to 5 with descriptions.)
17. **Visual information:** Is visual explanation of concepts – through charts/graphs/images/videos, etc. – clear, logical, correct? (5 multiple-choice answers graded 1 to 5 with descriptions.)
18. **Credibility:** Does the app come from a legitimate source (specified in app store description or within the app itself)? (5 multiple-choice answers graded 1 to 5 with descriptions.)
19. **Evidence base:** Has the app been trialled/tested; must be verified by evidence (in published scientific literature)? (5 multiple-choice answers graded 1 to 5 with descriptions.)

Total quality score: A + B + C + D

SUBJECTIVE SECTION

Section E

Score out of 20 points

20. **Would you recommend this app to people who might benefit from it?** (5 multiple-choice answers graded 1 to 5 with descriptions.)
21. **How many times do you think you would use this app in the next 12 months if it was relevant to you?** (5 multiple-choice answers graded 1 to 5 with descriptions.)
22. **Would you pay for this app?** (5 multiple-choice answers graded 1 to 5 with descriptions.)
23. **What is your overall star rating of the app?** (5 multiple-choice answers graded 1 to 5 with descriptions.)

Appendix 2. Peer Review from the *Journal of Medical Internet Research* – JMIR

Form for Health Apps, 2014
Available at: tinyurl.com/appsform

Category	Parameters/criteria (completed using the form on the website)
About the applicant	Name, email, role, other persons who helped fill in the questionnaire
About the app	Name, version, last update, update/revision cycles, platforms, countries, URL, tester access instructions, URL of creator, URL(s) for general information and user manual, URL(s) of screenshots, copyright, third-party URLs, hardware components, price, name of creator/manufacturer, type of creator, main contact, main contact email, main contact role, name of contributors/organisation, link to contributors page, user support.
Details about the app	Main target audience, specific targets in more detail, main purpose of the app, similar competitors and differences, classification (electronic medical textbooks, health tracking and evaluation, practice management, generic non-medical aids, electronic health record systems, medical diagnosis, treatment of disease, prevention of disease, affects the structure or any function of the body, accessory to a medical device, other), key features and functionalities, authors of information and credentials, author disclosure in app, financial disclosure and funding sources, financial disclosure in app, conflicts of interest, conflicts of interest disclosure in app, contraindications, contraindications disclosure in app, known limitations, potential risks.
Security and privacy	Privacy or confidential data policy, privacy or confidential data policy location in app, privacy settings, privacy access logs with URL or menu point, security of transmission protocols.
FDA approval	FDA approval status, details of application or no approval.
Development and testing process and evidence base	Level of formative evaluation or user-centred development, formative evaluation and key publications, evidence level of the app (not peer-reviewed or evaluated, peer review planned, peer-reviewed, observational study in progress, observational study completed, randomised trial (pilot/small) in progress, randomised trial (pilot/small) completed, randomised trial (large scale) in progress, randomised trial (large scale) completed), primary and secondary endpoints of the studies, trial registration, theory or evidence behind the app's content, theory/evidence base key publications, peer review key publications, reviews in independent journals or blogs, observational outcome evaluation key publications, randomised outcome evaluation key publications, key findings of outcome studies by credible publications, additional information.

URL: *uniform resource locator*, FDA: Food and Drug Administration.

Appendix 3. Literature Search

▶ Bibliographic databases

The literature search was limited to publications in English and French, using the following sources:

- MEDLINE database for international literature;
- Banque de données en santé publique [Public Health Database] for French-language literature;
- Cochrane Library;
- websites that publish guidelines, technology assessment reports or economic evaluation reports;
- websites that are competent in the subject matter studied, including app/SD evaluation sites and news sites.

The database query strategy specified search terms, Boolean operators and search period for each question and/or type of study.

The search terms used were either thesaurus terms (descriptors) or free terms (from the title or abstract). They were combined with terms describing the types of studies.

The table below summarises the steps taken, in order, for each query in the MEDLINE database. The total number of references obtained by querying this bibliographic database was 643.

Search strategy in the MEDLINE database

Type of study/subject	Terms used	Period
Guidelines & consensus conferences		01/2005 – 12/2015
Step 1	(Cell Phones OR Mobile Applications)/maj OR (mobile application OR mobile applications OR mobile app OR mobile apps OR smartphone application OR smartphone applications OR Smartphone app OR Smartphone apps OR app stores OR Mobile Medical Application OR Mobile Medical Applications OR medical apps OR medical app OR standalone software OR health apps OR health app OR mhealth OR mobile health)/ti,ab OR (ehealth OR apps OR app)/ti OR ((Medical Informatics Applications/maj OR Software/Maj:NoExp OR (application OR applications OR health OR medical)/ti) AND (mobile OR smartphone OR phone)/ti)	
AND		
Step 2	(guide OR guidance* OR recommendation* OR guideline* OR statement* OR consensus OR position paper)/ti OR (Guidelines as topic OR health planning guidelines OR Practice Guidelines as topic OR Consensus Development Conferences as topic OR Consensus Development Conferences, NIH as topic)/de OR (practice guideline OR guideline OR Consensus Development Conference OR Consensus Development Conference, NIH OR Government Publications)/pt	
Meta-analyses & systematic reviews		01/2010 – 12/2015
Step 1		
AND		
Step 3	(metaanalys* OR meta-analys* OR meta analysis OR systematic review* OR systematic overview* OR systematic literature review* OR systematical review* OR systematical overview* OR systematic literature review* OR systematic literature search)/ti,ab OR meta-analysis as topic/de OR meta-analysis/pt OR cochrane database syst rev/so	

Type of study/subject	Terms used	Period
App assessment		01/2010 – 12/2015
Step 1		
AND		
Step 4	(quality control framework OR regulatory framework OR evaluation framework OR ehealth framework OR Mobile App Rating scale OR MARS OR scoring OR quality assessment)/ti,ab OR (framework OR frameworks OR certificat* OR label* OR standard OR criteria)/ti OR Software Validation/de	
OR		
Step 5	(mhealth OR mobile health OR apps OR app OR standalone software)/ti AND (evaluat* OR Assessment)/ti	

: wildcard; de: descriptor; ti: title; ab: abstract; pt: publication type; so: journal title

▶ Sites consulted

- **Examples of health app evaluation/classification portals or sites**
  - *Agency of Healthcare Quality of Andalusia (appSaludable)*: www.calidadappsalud.com/distintivo/catalogo
  - *AppCheck*: www.appcheck.de
  - dmd Santé (dmdpost): www.dmd-sante.com
  - *HealthOn*: www.healthon.de
  - *iMedicalApps* (iPrescribeApps): www.imedicalapps.com
  - *IMS Health* (AppScript): www.imshealth.com
  - *Medappcare*: www.medappcare.com/conseil-scientifique
  - *myhealthapps.net*: myhealthapps.net/about
  - *UK's National Health Service: NHS choices (Health Apps Library)*: apps.nhs.uk/review-process/#
- **Examples of sites that list health apps (without evaluating them)**
  - *Eat right*: www.eatrightpro.org/resources/media/trends-and-reviews/app-reviews
  - Infirmier.com: www.infirmiers.com/ressources-infirmieres/documentation/tour-horizon-de-quelques-applications-mobiles-bien-utiles.html
  - *National Health Portal: mhealth*: www.nhp.gov.in/mobile-apps
  - *UF Diabetes Institute: mhealth*: diabetes.ufl.edu/my-diabetes/diabetes-resources/diabetes-apps/
  - *US department of Veterans Affairs: VA mobile health (VA App Store)*: mobile.va.gov
  - *Zur Institute: Mental Health Apps*: www.zurinstitute.com/mentalhealthapps_resources.html
- **mHealth news sites**
  - Buzz-esanté - le blog du digital santé: linkis.com/buzz-esante.fr/Ab5Ye
  - *Connected doctors*: www.theconnectedmag.fr
  - DSIH e-sante: www.dsih.fr
  - *GeekMedical*: www.geekmedical.fr
  - Le monde de la e-santé: lemondedelaesante.wordpress.com
  - *MedCityNews*: medcitynews.com
  - *mHealth News*: www.mhealthnews.com
  - *Mobihealthnews*: mobihealthnews.com
  - objetconnecte.net: www.objetconnecte.net/category/sante-connectee/
  - Proxima mobile: www.proximamobile.fr/article/france-un-guide-mobile-pour-800-applications-de-sante?cat=none
  - *Smart Phone Healthcare*: www.smartphonehc.com
- **Other sites consulted**
  - Agence des systèmes d'information partagés de santé - ASIP Santé: www.asipsante.fr
  - Agence fédérale des médicaments et des produits de santé - AFMPS: www.fagg-afmps.be/fr/
  - Agence nationale de sécurité du médicament et des produits de santé - ANSM: ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/Logiciels-et-applications-mobiles-en-sante/%28offset%29/1
  - *Agency for Healthcare Research and Quality* - AHRQ: www.ahrq.gov
  - *Alberta Medical Association*: www.topalbertadoctors.org

- *American College of Physicians* – ACP: www.acponline.org/clinical/guidelines/index.html#acg
- *Attorney General* (État de Californie): www.attorneygeneral.jus.gov.on.ca/french/default.asp
- Bibliothèque médicale Lemanissier: www.bmlweb.org/consensus.html
- Bibliothèque interuniversitaire de médecine - BIUS
- *CATAAlliance* [*CATA Mobile Health Advisory Board* (MHAB)]: www.cata.ca/Communities/MHAB/
- Catalogue et Index des sites médicaux francophones - CISMeF: www.cismef.org
- Centre fédéral d'expertise des soins de santé - KCE: kce.fgov.be/fr
- Commission nationale de l'informatique et des libertés - CNIL: www.cnil.fr
- Conseil de l'Europe: www.coe.int/web/portal/home
- Conseil National de l'Ordre des Médecins - CNOM: www.conseil-national.medecin.fr/e-sante/les-publications-1143
- Contrôleur européen de la protection des données - EDPS/CEPD: secure.edps.europa.eu/EDPSWEB/
- E.sante.gouv: esante.gouv.fr
- *European Commission*: ec.europa.eu/digital-agenda/en/mhealth
- *Euroscan*: www.euroscan.bham.ac.uk
- *Food and Drug Administration* - FDA: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/default.htm
- *Groupe Speciale Mobile Association* - GSMA: www.gsma.com
- *Guidelines International Network* - GIN: www.g-i-n.net
- *HealthIT.gov*: www.healthit.gov/patients-families/health-conditions
- *Institute for Clinical Systems Improvement*: www.icsi.org
- *International Medical Device Regulators' Forum* - IMDRF: www.imdrf.org
- *International mHealth Standardization Consortium* - IMHSC: www.imhsc.org/legislation_3.html
- *International Network of Agencies for Health Technology Assessment* - INAHTA: www.inahta.org
- *CRD databases*: www.crd.york.ac.uk/crdweb/
- *Medical Technology Association of Australia* - MTAA: www.mtaa.org.au/homepage
- *Medicines or Healthcare products Regulatory Agency* - MHRA: www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
- *National Guideline Clearinghouse* - NGC: www.guideline.gov
- *National Health and Medical Research Council* - NHMRC: www.nhmrc.gov.au/publications/index.htm
- *National Institute for Health and Clinical Excellence* - NICE: www.nice.org.uk/page.aspx?o=home
- *National Institute of Health* - NIH: obssr.od.nih.gov/scientific_areas/methodology/mhealth/
- *National Telecommunications and Information Agency* - NTIA: www.ntia.doc.gov
- *New Zealand Guidelines Group* - NZGG: www.nzgg.org.nz
- *NHS Evidence*: www.evidence.nhs.uk
- Observatoire de la m-santé: www.ifop.com/?option=com_offer&id=186
- Organisation Mondiale de la Santé - OMS: www.who.int/fr
- *Privacy Rights Clearing House Association*: www.privacyrights.org/content/about-privacy-rights-clearinghouse
- *Scottish Intercollegiate Guidelines Network* - SIGN: www.sign.ac.uk/index.html
- SFT - Société française de télémédecine: www.sft-antel.org/site/accueil.html
- *The Cochrane Library*: www.mrw.interscience.wiley.com/cochrane/cochrane_search_fs.html
- *Therapeutic Goods Administration* - TGA: www.tga.gov.au
- *Tripdatabase*: www.tripdatabase.com/index.html

In addition, Twitter was monitored for the following keywords: #mhealth OR "mobile health" OR "m santé" OR #msanté. Relevant Twitter accounts in the field were also followed throughout the study.

Appendix 4. List of Tables

Table 1. Non-exhaustive list of sites that evaluate health apps/SDs in various countries (in alphabetical order)

Table 2. Tailoring the guidelines using a risk matrix

Table 3. List of criteria related to informing users

Table 4. List of criteria related to products' health content

Table 5. List of criteria related to products' technical content

Table 6. List of criteria related to product security and reliability

Table 7. List of criteria related to product use

Appendix 5. Glossary

Anonymisation
The process of removing all links to a person. Personal data processing, which is usually forbidden by French law, may be authorised by CNIL if sensitive information for processing undergoes a prompt, recognised and legally compliant anonymisation procedure.

Big data
The phenomenon of big data has been under discussion for several years now. With the development of new technologies, the internet and social networks in the past twenty years, more and more digital data are being created: texts, photos, videos, etc. Today, the enormous volumes of digital data produced, combined with ever-increasing storage capacities and increasingly sophisticated real-time analysis tools, offer unrivalled possibilities for using information. All processed data that meet the definition of "big data" have three key characteristics: volume, velocity (speed) and variety.

Consent
Consent of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.

Cross-site request forgery
Abbreviated as CSRF (sometimes pronounced sea-surf in English). The aim of this attack is to send an authenticated user a forged HTTP request that points to an action within a site, so that the user executes it unaware, using their own access rights. The user thus becomes complicit in an attack without even realising it. Once the attack has been activated by the user, a large number of authentication systems are bypassed (source: French Wikipedia).

eHealth
The application of information and communications technology to any health-related activity.

Empowerment
Empowerment means giving individuals or groups more power to act on the social, economic, political or ecological conditions they are experiencing (source: French Wikipedia).

Geolocation
Technology allowing the location of an object or person to be determined with some precision. This technology generally uses the GPS system or communication interfaces of a mobile phone. The uses and purposes of geolocation are many, from navigation assistance to bringing people together, and also include real-time management of human resources and company vehicles, etc.

Mobile health (mHealth)
Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.

PDA phone
Mobile telephone combined with a personal digital assistant.

Personal data breach
A breach of security leading to the accidental or unlawful destruction, loss, alteration, unau-thorised disclosure of, or access to, personal data transmitted, stored or otherwise pro-cessed.

Personal data
Any information relating to an identified or identifiable natural person ("data subject"); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Phishing
Phishing or spoofing is a technique used by fraudsters to obtain personal information with the aim of impersonating someone's identity. The technique involves making the victim believe that he or she is in contact with a trusted third party – bank, government, etc. – to extract personal information: password, credit card number, date of birth, etc. It is a form of cyber attack that uses social engineering. It may take place through email, forged websites or other electronic media (source: French Wikipedia).

Pseudonymisation
The processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

Quantified self
The quantified self designates the practice of "self-tracking" and refers to a movement that started in California, which involves getting to know oneself better by measuring data related to one's body and activities.

Recipient
A natural or legal person, public authority, agency or another body, to which personal data are disclosed, whether a third party or not. However, public authorities which may receive personal data in the context of a particular inquiry in accordance with EU law or Member State law shall not be regarded as recipients; the processing of those data by those public authorities shall be in compliance with the applicable data protection rules according to the purposes of the processing.

Sensitive data
Information about racial or ethnic origin, political, philosophical or religious views, trade union membership, health or sexual activity. In principle, sensitive data cannot be collected and used without the individuals' specific consent.

Smartphone
A smartphone is a mobile telephone with a touchscreen, digital camera, and the functions of a personal digital assistant and portable computer (source: French Wikipedia).

Third party
A natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorised to process personal data.

Treatment
Any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

Appendix 6. Working Method

This document was created between November 2015 and September 2016. It was produced for the Haute Autorité de Santé (HAS) in the Department for Evaluating the Appropriateness of Care and Improving Practices and Pathways (SA3P) by Mr Pierre Trudelle, the project lead, in collaboration with Mr Marc Fumey, Assistant Head of Department, and with the help of a working group and two external experts.

Administrative support was provided by Ms Michèle Le Moigne, Management Assistant, with the help of Ms Isabelle Le Puil, Management Assistant, for the GRaAL interface (streamlined management of review group opinions).

A call for candidates to take part in the working group was open online between November 2015 and 31 December 2015 (project outline: 19 November 2015). The office of the HAS Physician Practice and Care Pathways Committee (CPP) decided on the final composition of the working group and defined the remits of the review group and stakeholder group at a meeting on 10 February 2016. Declarations of interests by the working group members are available on the HAS website (www.has-sante.fr).

The working group met on 22 March 2016, 3 May 2016 and 6 September 2016 for a full day. A review group, a group of stakeholders and a group from the industry strategic committee (called Working Group 28 in reference to “measure 28” of the industry strategic contact) presented scores using a Likert scale from 1 (strongly disagree) to 9 (strongly agree) for all criteria selected, using the HAS GRaAL interface, between the second and third meetings of the HAS working group. The review group was made up of members selected during the CPP (mainly people who were not selected during the call to participate in the working group) and individuals suggested by the working group.

The literature search was carried out by Ms Marie Georget, documentalist, and Ms Laurence Frigère, assistant documentalist, under the supervision of Ms Frédérique Pagès, Head of the HAS Archive and Literature Monitoring Department.

The working group contributed to writing the technical parts of this guide, with support during their last meeting from experts from ANSSI and CNIL. The selection and analysis of the literature was done by Mr Pierre Trudelle. The European guidelines on the subject were drawn up in parallel with this document. Mr Pierre Trudelle took part in that working group (*mHealth assessment guidelines*) to provide and translate the French material and to synchronise information between the groups.

The HAS Legal Department played a role in writing the legal section and reviewing the criteria under the supervision of Ms Ariane Sachs, lawyer; Mr Emmanuel Planchet, lawyer; and Ms Christine Vincent, Head of the HAS Legal Department.

The document was laid out by Mr Eric Darvoy, layout artist and graphic designer, under the supervision of Ms Annie Chevallier, Publishing and Distribution Manager in the Public Relations and Information Department.

The document was submitted to the CPP on 27 September 2016.

It was submitted to the HAS Board on 26 October 2016.

Appendix 7. Participants

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