Standardised assessment of evidence supporting the adoption of mobile health solutions

A Clinical Consensus Statement of the ESC Regulatory Affairs Committee

Developed in collaboration with the European Heart Rhythm Association (EHRA), the Association of Cardiovascular Nursing & Allied Professions (ACNAP) of the ESC, the Heart Failure Association (HFA) of the ESC, the ESC Young Community, the ESC Working Group on e-Cardiology, the ESC Council for Cardiology Practice, the ESC Council of Cardio-Oncology, the ESC Council on Hypertension, the ESC Patient Forum, the ESC Digital Health Committee, and the European Association of Preventive Cardiology (EAPC)

Caiani EG*[1,2], Kemps H*[3,4], Hoogendoorn P*[5], Asteggiano R[6,7], Böhm A[8,9], Borregaard B[10,11,12], Boriani G[13], Brunner La Rocca HP[14,15], Casado-Arroyo R[16], Castelletti S[2], Christodorescu R[17,18], Cowie MR[19], Dendale P[20,21], Dunn F[22,23], Fraser AG[24], Lane DA[25,26], Locati ET[27], Małaczyńska-Rajpold K[28,29], Merșa C[30], Neubeck L[31], Parati G[2,32], Plummer C[33,34], Rosano G[35,36], Scherrenberg M[21,37], Smirthwaite A[38], Szymanski P[39,40].

*: shared co-first authorship

1 Department of Electronics, Information and Bioengineering, Politecnico di Milano, Milan, Italy

2 IRCCS Istituto Auxiologico Italiano, San Luca Hospital, Milan, Italy

3 Department of Cardiology, Maxima medical centre, Veldhoven, The Netherlands

4 Department of Industrial design, Eindhoven university of technology, Eindhoven, The Netherlands

5 National eHealth Living Lab, Leiden University Medical Center, Leiden, The Netherlands

6 Department of Medicine and surgery, University of Insubria, Varese, Italy

7 Department of Cardiology, LARC - Laboratorio Analisi e Ricerca Clinica, Turin, Italy

8 Premedix Academy, Bratislava, Slovakia

9 3rd Department of Internal Medicine, Comenius University in Bratislava, Bratislava, Slovakia

10 Department of Cardiology, Odense University Hospital, Odense, Denmark

11 Department of Clinical Research, University of Southern Denmark, Odense, Denmark

12 Department of Cardiac, Thoracic and Vascular Surgery, Odense University Hospital, Odense, Denmark

13 Cardiology Division, Department of Biomedical, Metabolic and Neural Sciences, University of Modena and Reggio Emilia, Policlinico di Modena, Modena, Italy

14 Department of Cardiology, Maastricht University Medical Centre, Maastricht, The Netherlands

15 Cardiovascular Research Institute, University of Maastricht, Maastricht, The Netherlands

16 Department of Cardiology, Hopital Erasme, Université Libre de Bruxelles, Brussels, Belgium

17 Department V-Internal Medicine, University of Medicine and Pharmacy V.Babes Timisoara, Timisoara, Romania

18 Research Center, Institute of Cardiovascular Diseases, Timisoara, Romania

19 Late CVRM, Biopharmaceuticals R&D, Astrazeneca, Boston MA, United States of America

20 Department of Medicine and Life Sciences, Hasselt University, Hasselt, Belgium

21 Department of Cardiology, Hartcentrum Hasselt, Hasselt, Belgium

22 Active Medical Devices, BSI, Milton Keynes, United Kingdom

23 team-nb, Sprimont, Belgium

24 School of Medicine, Cardiff University, Heath Park, Cardiff, United Kingdom

25 Department of Cardiovascular Medicine and Liverpool Centre for Cardiovascular Sciences, University of Liverpool, Liverpool, United Kingdom

26 Department of Clinical Medicine, Aalborg University, Aalborg, Denmark

27 Department of Arrhythmology & Electrophysiology, IRCCS Policlinico San Donato, San Donato Milanese, Milano, Italy

28 Department of Cardiology, Lister Hospital, East and North Hertfordshire NHS Trust, London, United Kingdom

29 Heart Division, Arrhythmia Section, Royal Brompton Hospital, Guy's and St Thomas' NHS Foundation Trust, London, United Kingdom

30 Rhea, Research Center for Heritage and Anthropology, West University of Timișoara, Timișoara, Romania

31 Centre for Cardiovascular Health, Edinburgh Napier university, Edinburgh, United Kingdom

32 Department of Medicine and Surgery, University of Milano-Bicocca, Milano, Italy

33 Department of Cardiology, The Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, United Kingdom

34 Faculty of Medical Sciences, Newcastle University, Newcastle upon Tyne, United Kingdom

35 CAG Cardiovascular, St George's University Hospital, London, UNITED KINGDOM

36 Cardiology, San Raffaele Cassino Hospital, Cassino, ITALY

37 Faculty of Medicine, University of Antwerp, Antwerp, Belgium

38 Intelligence & Innovation, RQM+, Nottingham, United Kingdom

39 Center for Postgraduate Medical Education, Marymoncka, Warsaw, Poland

40 Clinical Cardiology Center, National Institute of Medicine MSWiA, Wołoska, Warsaw, Poland

Corresponding author:

Prof. Caiani Enrico Gianluca, MS, PhD, FESC

Politecnico di Milano, Electronics, Information and Biomedical Engineering Dpt.

P.zza L. da Vinci 32, 20133 Milano (MI), Italy

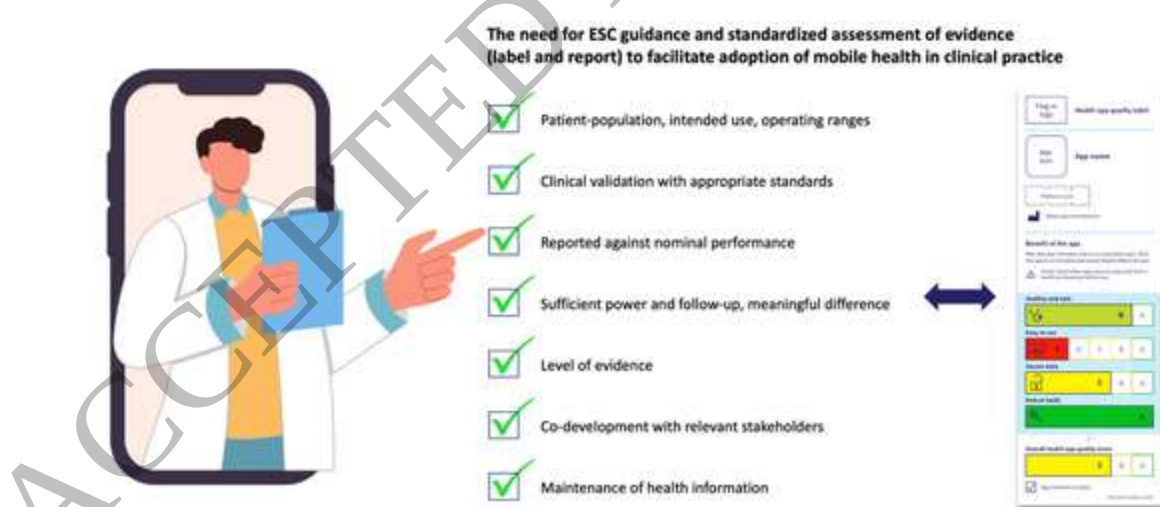
Email: enrico.caiani@polimi.it Phone: +39.3387163426

Abstract

Mobile health (mHealth) solutions have the potential to improve self-management and clinical care. For successful integration into routine clinical practice, healthcare professionals (HCPs) need accepted criteria helping the mHealth solutions' selection, while patients require transparency to trust their use. Information about their evidence, safety and security may be hard to obtain and consensus is lacking on the level of required evidence. The new Medical Device Regulation is more stringent than its predecessor, yet its scope does not span all intended uses and several difficulties remain. The European Society of Cardiology Regulatory Affairs Committee set up a Task Force to explore existing assessment frameworks and clinical and cost-effectiveness evidence. This knowledge was used to propose criteria with which HCPs could evaluate mHealth solutions

spanning diagnostic support, therapeutics, remote follow-up and education, specifically for cardiac rhythm management, heart failure and preventive cardiology. While curated national libraries of health apps may be helpful, their requirements and rigour in initial and follow-up assessments may vary significantly. The recently developed CEN-ISO/TS 82304-2 health app quality assessment framework has the potential to address this issue and to become a widely used and efficient tool to help drive decision-making internationally. The Task Force would like to stress the importance of co-development of solutions with relevant stakeholders, and maintenance of health information in apps to ensure these remain evidence-based and consistent with best practice. Several general and domain-specific criteria are advised to assist HCPs in their assessment of clinical evidence to provide informed advice to patients about mHealth utilisation.

Graphical abstract



keywords: mobile health; clinical evidence; requirements; assessment; standardisation

1. Definition of the problem

1.a Guiding patients towards the use of mHealth solutions

Mobile health (mHealth) is defined by the World Health Organization's (WHO) Global Observatory for eHealth 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".

The availability of mHealth solutions on the market and their widespread use in the general population is constantly increasing. The mHealth solutions typically include wearables and/or apps for information, prevention, promotion, data collection, treatment, and maintenance of health. During the COVID-19 pandemic, mHealth solutions were presented as playing a positive role in public health, mitigating the impact of COVID-19 on individuals and health systems [1,2]. Accordingly, the mHealth market size, valued at around USD 111.5 billion in 2022, is projected to grow at over 22% compound annual growth rate through 2032 [3].

The mHealth solutions have the potential of empowering patients to assume a more active role in monitoring and managing their chronic conditions and therapeutic regimens, as well as providing healthcare professionals (HCPs) with more data and enabling more frequent follow-ups than in classical care. However, as the significance of end-user involvement is fundamental for technology adoption in healthcare [4], their success in being integrated into routine clinical practice is highly related to their adoption by HCPs [5-6].

In practice, suggesting mHealth solutions to patients by HCPs depends on personal factors, institutional strategies and regional/national regulations/reimbursement. Among the factors that are important for HCPs when considering whether to suggest an mHealth solution to patients, the presence of a stamp of approval from a regulatory agency and the presence of published studies to demonstrate safety and clinical effectiveness have been identified as important determinants [7]. Indeed, guidance by an HCP represents a significant factor motivating a patient's adoption of mHealth [8]. This requires a degree of responsibility for the HCP, which could include a commitment to regularly review the data collected by the patient and to communicate digitally with him/her, often without specific compensation or reimbursement for this additional work if the mHealth solution is not integrated as part of a standard care pathway, with the need for such a solution to reduce the time required for the involvement of the HCP and allow patients to provide feedback on their conditions. In addition, the patient may assume that the suggested solution is reliable, accurate, safe, and useful for his/her condition so that, if its use were to create a negative impression, this could also have a negative impact on the patient-HCP relationship.

In this context, the incorporation of artificial intelligence (AI) methodologies within mHealth solutions, besides the added potential clinical value, could generate additional concerns, both practical and ethical, such as data privacy, physician dependency on poorly understood AI software, bias in data used to create algorithms, and changes to the patient–physician relationship [9]. Future implementation of the recently approved EU AI Act [10] may shed more light in this area.

Several cardiovascular (CV) clinical practice guidelines have started to describe and discuss the use of mHealth solutions before there are accepted criteria to help HCPs or patients to select the mHealth solutions that could be clinically useful for a specific CV disease. This is complicated by the fact that these solutions are mainly consumer-centred and consumer-driven [11-12], and available through company websites or app stores either for free (the business model implying the creation of value from the user information and data) or by payment of a fee (for a single purchase or as recurring charges).

The ESC Regulatory Affairs Committee set up a Task Force including clinical experts, patient representatives and members with recent experience of working in a notified body (NB), to propose both general and specific criteria with which HCPs could evaluate the available clinical evidence for mHealth solutions to provide informed advice to patients. In this process, existing assessment frameworks and the experience of other medical associations were considered. This report provides directions for specific fields of CV clinical practice (such as the management of heart failure, diagnosis of atrial fibrillation, and preventive cardiology) in which mHealth solutions are potentially useful for CV patients.

1.b Access to mHealth solutions

For both patients and HCPs, most apps used in mHealth solutions are accessed through mobile app stores and websites. Currently (at Q2 2023), there are about 300,000 health-related apps across both Apple App Store (82,899 in Health & Fitness and 195,799 in Lifestyle categories) and Google Play Store (95,873 in Health & Fitness and 121,390 in Lifestyle categories), including over 10,000 behavioural health apps, focused on self-diagnosis, lifestyle management, or management of chronic disease [13]. Although convenient in principle, by providing democratized access at low to no cost to a broader population across the globe, this route of access presents multiple disadvantages from a search and quality perspective [14]: firstly, app stores are not designed for the identification of the most appropriate apps for patients or HCPs. Apps with potential healthcare implications are listed generically under a category chosen by the developer – usually "Lifestyle" or "Health & fitness" – which does not allow more specific searches for a clinical domain or filtering for certified medical device (MD) software. In addition, query results are prioritized according to criteria determined by the App Store (for Android, relevance, engagement, and quality), rather than by clinically relevant characteristics, such as the specific target of an app or the presence of evidence of safety and efficacy in peer-reviewed publications.

Secondly, publication in an app store does not imply that its clinical content, performance accuracy, specificity, or effectiveness, have been validated, or that safety risks have been assessed [15]. Generally, mHealth apps lack systematic examination of their reliability, validity, feasibility, and clinical utility. They lack data on authenticity (e.g. functionality, user acceptability and satisfaction), which limits their endorsement by HCPs [16] and their clinical value. Moreover, apps often have vague or misleading descriptions of their intended purpose, even when certified as a MD. Lastly, the level of usability and accuracy of apps are highly variable and not always well documented [17-18].

Access to mHealth solutions, including wearables such as smart watches, is further complicated by the fact that they can assume the role of a life-style gadget and/or that of a MD, depending on the model and the country in which they are sold. Many wearables are now fully accessible through general or specific marketplaces without any prescription. Even when they are advertised as MD, information about efficacy, certification class and relevant clinical evidence is not always available. In addition, operational limitations (e.g. not for users below or above a certain age, not able to provide reliable results outside a certain range of the parameter of interest, not suitable for users with certain conditions) may be visible only through detailed reading of a user manual rather than on the webpage where the product is advertised.

1.c Data security

Data security represents another important aspect that is relevant to the use of mHealth. Sharing of personal data could occur without full transparency to the end-user, often based on vague or poorly written consent forms. In fact, approximately 95% of health apps have a security or privacy risk, which varies with the app's functionality, yet apps with the greatest risk may also have the greatest clinical utility [19,20]. A recent analysis of the health app market showed that 88% of 20,991 Android health apps had tracking capabilities, and 80% of all data collection operations were on behalf of third-party services [21]. Therefore, it is important that both patients and HCPs are aware of these privacy risks. Clinicians should always inform patients about risks when guiding the patient towards the use of mHealth interventions, and there is a clear need for better awareness of current regulation, and relevant accountability for the different actors involved in sharing personal data [22]. It is noteworthy that, for mHealth solutions collecting data from EU citizens, the EU General Data Protection Regulation 2016/679 [23] applies. This includes, among others, its principle of data minimization (i.e., the collection of personal information needs to be limited to what is directly relevant and necessary to accomplish a specified purpose). Also, data should be retained only for as long as is necessary to fulfil that purpose, and data subjects have the "right to be forgotten" (i.e., the data subject has the right to obtain the erasure of personal data at any time if consent is withdrawn), and the "right of access" (i.e., individuals can request a copy of any of their personal data which are processed). As the development of new technology implies evolving challenges for data security and privacy, including cybersecurity threats, it is expected that regulatory authorities would apply current legislation, both at EU and national level, and as well as mHealth developers who would minimize such challenges [24].

1.d Notified bodies, certification process and open problems

Medical devices of Class IIa and higher risk have their technical files, clinical evaluation, performance and safety reviewed by a Notified Body (NB), while Class I devices are self-certified and CE marked by innovators themselves. Under the Medical Device Directive (93/42/EC) (MDD), the majority of mHealth solutions were classified only as Class I. Since the application of the EU Medical Device Regulation (MDR, 2017/745) and its Rule 11, regulatory requirements for mHealth apps are more stringent. Class IIa now represents the entry class for mHealth solutions with a medical purpose, with only few devices remaining in Class I. Some devices have been up-classified to Class IIb and Class III [25, 26].

These changes have caused some difficulties:

1. Not all innovators are aware of the MDR [27]
2. Among those that are aware, many struggle to classify their device properly or to define their intended purpose fully, despite the further guidance in MDCG 2019-11, and MDCG 2021-24 [26, 28].
3. The experience of certifying mHealth solutions as class IIa or higher-risk devices with NB has been limited, especially for clinical performance evaluation [29]
4. Where the required level of supporting data for clinical evidence has not been predefined, it is based on route of conformity and existing guidance, such as MDCG 2020-1[29], MDCG 2020-5 [30]. The criteria listed in the guidance document are very generic and non-specific.
5. There is also a lack of clarity as to which changes in software require recertification or review by the notified body. This could require the production of additional clinical evidence related to novel technologies and changes to their intended purpose or clinical use.

Because of these challenges, differences in assessments may exist both within and between NBs, and input from medical professional associations (e.g. clinical guidelines) could be needed to improve the application of the new Regulation, in particular for novel technologies.

The ambiguity and fragmentation of the regulatory framework have led to an increase in regulatory workload and a steep learning curve for both innovators and NBs. The shortage of expertise and the multitude of MDD certifications expiring in 2023/2024 could have a significant impact on time to market for new mHealth solutions. This problem has been temporally delayed by the Regulation (EU) 2023/607 [31], that has extended the transitional periods to the new rules for devices covered by a certificate or a declaration of conformity issued before 26 May 2021, under some conditions, and with terms depending on the risk class of the device . Combined with the budgetary impact of the certification process, this may discourage innovation and decrease access for patients to effective products. Innovators may go out of business, move out of Europe to the US where regulation is currently less strict and less expensive, or downgrade the intended purpose of their products [27]. The future implementation of the proposed Artificial Intelligence (AI) Regulation [10] may also exacerbate this issue.

1.e. What are the needs from a patient point of view?

The regulations for mHealth solutions must be transparent for patients to have confidence in their use. As described by a patient representative: "*It's important for me, that this is regulated in the same way my medication is. If this is part of my treatment, I should be able to trust that everything in the app is correct*." Although mHealth apps have the potential to support patients by education, improvement of adherence to treatment and self-management [32], there are several concerns related to their use in cardiology from a patient's perspective (see Figure 1):

1. There must be trust in the content of mHealth solutions, with clinical evidence to support their claims and clear rules related to privacy, use of data, consent and other legal aspects of their use [33-35].
2. It is essential that it is clear whether patients can access the data entered in an mHealth app, and how HCPs can use and store these data for the benefit of the patient.
3. Patients should have information about the credibility of the company producing an mHealth solution, and about its commitment to long-term support of the mHealth app once it is on the market.
4. Documentation on the accuracy, reliability and overall app usability must be provided.

5. To ensure the successful implementation and use of an app, the design processes should involve patients and clinicians, from concept to release – this is essential for the performance and safety of mHealth solutions. It is also essential for user retention, which is low for mHealth solutions over 3-6 months, particularly if they have not been developed to meet specific patient (and provider) expectations, preferences, needs and requirements [36-37].
6. Concerning the design of the software and its user interface, the solution should be intuitive, include precise functions and layouts, and be easy to use regardless of the eHealth literacy skills of the target user(s) [38-39]. The potential need for education and training in the use of the mHealth solutions must also be considered. This can be relevant for both patient users and HCPs guiding them, to ensure that the solution is used as intended and the provided data are interpreted correctly.
7. The costs/reimbursement rules of accessing the solution and/or provided services may also play a role in its accessibility and should therefore be transparent.
8. When using mHealth solutions as with medication dosage, the risk of over-monitoring leading to stress and anxiety should be considered. A guide on “how often” and “how much” should be included and provided by the HCP. The purpose of using the app should always be clear and specific.

Figure 1. Aspects of mHealth solutions important both from patient’s and HCP’s point of view

- Trust in content with clinical evidence to support claims
- Accessibility of inserted data
- Company credibility
- Data about accuracy, reliability and usability
- Co-design including patients and clinicians
- Intuitive and easy to use user interface
- Transparent costs
- Clear user guide and specific purpose for using it

2. How to define and where to find the right mHealth solution?

2.a Public assessment schemes and curated libraries

The World Health Organization, the Norwegian Centre for E-Health Research [40], and later, the European mHealth Innovation and Knowledge Hub [41] have investigated mHealth assessment frameworks to help identify safe and appropriate mHealth applications. Their findings show significant heterogeneity between the existing frameworks in the required level of clinical evidence: some were very technical and detailed, while others were more outcome-oriented. Only ten Western European countries were found to have one or more health app assessment frameworks and/or health app repositories. These repositories generally included at most a few dozen apps. A recent article in Nature compared health app policies in seven European countries, the United States, and Singapore, concluding that cross-national efforts are still needed to realize the benefits of health apps, and that even the front runners have yet to achieve an efficient certification process [42].

Several authorities have recently engaged in the development of frameworks, including France [43], Belgium [44, 45], Andalusia [46], Catalunya [47], Germany [48], Portugal [49], Switzerland [50], and the UK [51].

Reimbursement is an important issue influencing implementation of digital tools and apps in daily practice, as shown recently by a survey addressed to physicians [52]. The required type and quantity of evidence differs between countries. Most of the investigated cases presented clinical evidence, although some studies were non-randomized, and had a small sample size or suboptimal design. The choice of comparator was not always the standard of care (e.g. patient on the waiting list), and the magnitude of the treatment effect considered as sufficient was not always predetermined. The Belgian reimbursement scheme for mobile applications was updated on Oct 1, 2023, after evaluation of the previous process [53]. Germany is considered a European leader in this field: the German approach to digital health applications (DiGA) has allowed reimbursed prescription of approved therapeutic software products since October 2020. Although the German system does not strictly require RCTs, the evidence type for all but one of the reimbursed apps was an RCT, and for the remaining app a meta-analysis. Currently (Nov 2023) 55 apps are included for reimbursement: 24 of these apps are mental health apps, and only one cardiology app has been included so far [48]. However, the app prescription rate was found to be low, one year after implementation [54], probably due to the need to provide physicians with more education to increase their expertise and competence in recommending apps in the DiGA context [55].

2.b Private assessment schemes

There are several private mHealth app assessment schemes, but no international accreditation body exists to compare their quality and consistency. Without this, it is difficult to verify the (details of) assessment criteria used, and the level of expertise and independence of the assessors, as well as the criteria for clinical evidence applied in the assessment.

Amongst the larger of these schemes are:

- ORCHA (Organisation for the Review and Care of Health Applications): UK-based private company providing reviews, certification tools, digital libraries, implementation support, and education. ORCHA reports working in 12 countries around the world and being used by providers in 70% of UK National Health Service (NHS) regions.
- TherAppX: A Canadian private company founded by clinicians. Their platform uses software, screening by app analysts (privacy, usability, etc.), and in-depth review by a panel of clinicians to assess the over 170,000 apps available in Canada. TherAppX reports working with regional health authorities in Quebec.
- MedAppCare: a French start-up recently acquired by notified body DEKRA. Their service is accredited by the French Accreditation Committee COFRAC to certify smart health-connected health solutions.

All three organisations are collaborating in testing the certification scheme for the new CEN-ISO/TS 82304-2 technical specification (TS).

2.c Normative solutions: the new CEN-ISO/TS 82304-2:2021 technical specification

"CEN-ISO/TS 82304-2:2021 Health software – Part 2: Health and wellness apps – Quality and reliability" [56] was developed by the European Committee for Standardization (CEN) in response to a request from the European Commission. The initiative has achieved global cooperation with the International Organization for

Standardization (ISO) and the International Electrotechnical Commission (IEC). This Technical Specification (TS) provides a quality assessment framework, consisting of an 81-item questionnaire (available as Multimedia Appendix 8 from [57]) to be completed by the manufacturer of an mHealth app, including the required evidence, and a health app quality label (Figure 2) inspired by the effective EU energy label, the Nutri-Score front-of-pack nutrition label design, and the FDA over-the-counter drugs label.

The label displays the health app icon, name, platform compatibility (Apple, Google, web app), app manufacturer, the main benefit of the health app, when the app requires approval from a HCP before use, and color-coded scores from A (green, >90% of the weighted score) to E (red, < 60% of the weighted score) on four quality indicators which, after testing with people with low health literacy, have been called ‘Healthy and safe’, ‘Easy to use’, ‘Secure data’, and ‘Robust build’. An overall health app quality score is then computed by the weighted sum of the four quality aspects (with weights equal to 50%, 15%, 25%, 10%, respectively). Finally, the label shows the date the app was last checked by an (accredited) third-party health app assessment organization. The related health app quality report provides the answers to all the 81 questions, 67 of which are score-impacting, in the detail needed to give guidance about an app.

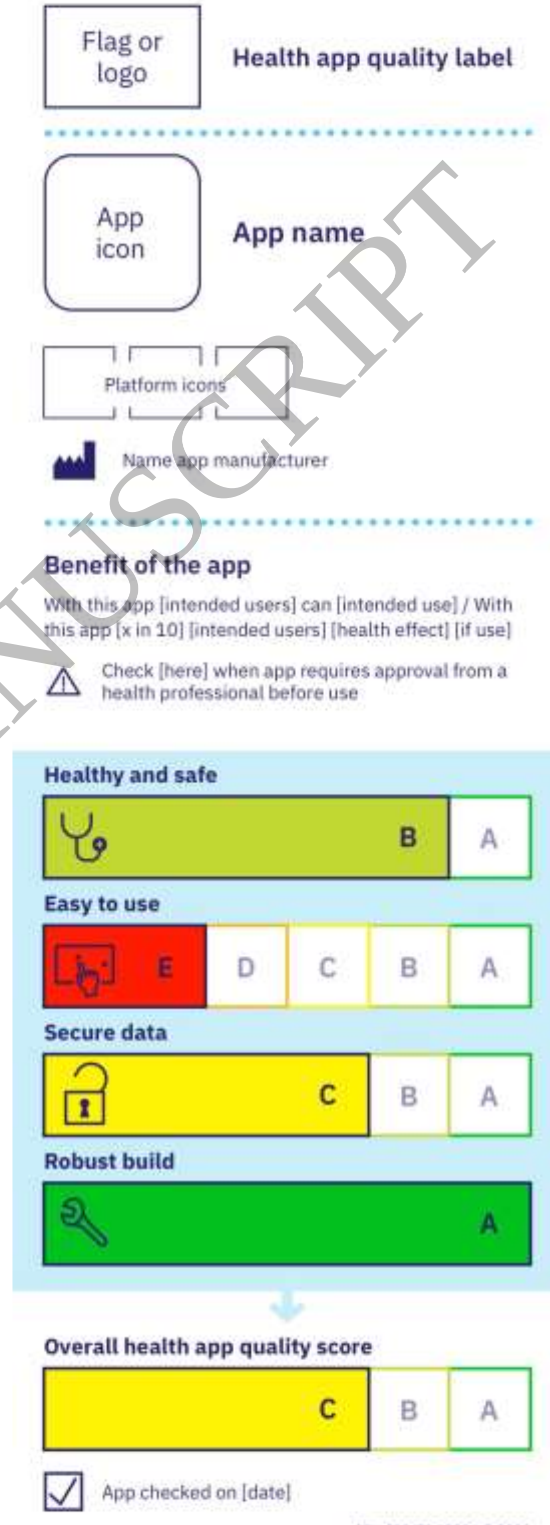


Figure 2 – The CEN-ISO/TS 82304-2 health app quality label, available as Multimedia Appendix 3 of [57].

The health app quality assessment framework was built on 26 existing frameworks and referenced 28 quality standards. A Delphi study of 83 experts from 8 stakeholder groups – including HCPs and patients/consumers from 6 continents, predominantly Europe – determined the assessment questions and their weighting [57]. The Dutch Ministry of Health has proposed a national assessment framework based on CEN-ISO/TS 82304-2 [58], Sweden is considering the framework [42], and Norway has already used it to assess wellness apps for its national repository [59]. In addition, France recognizes the potential of the framework for harmonization [43], and health authorities in Italy and Catalonia are part of the ongoing Horizon Europe Label2Enable project (Jun 2022-May 2024), which supports implementation of CEN-ISO/TS 82304-2 [60]. Label2Enable's main goal is to deliver the ISO/IEC 17067 compliant certification scheme (i.e. a handbook for CEN-ISO/TS 82304-2 health app assessments, aligned with EU level legislations and EU values, to be used by accredited assessment organizations). Also, guidance will be delivered on the level of detail in the health app quality report to enable HCPs to suggest apps confidently, together with the educational communication for patients to recognize and use the label, and findings of authorities' pilots and of HTA bodies and of insurers' round tables on the value of the TS as a basis for decision-making on reimbursement.

2.d Medical professional association initiatives

Medical associations are becoming increasingly active in offering help to HCPs to guide their patients in the proper use of mHealth.

The European Diabetes Forum (EUDF) recently created a roadmap for apps [61]. To realize their potential, EUDF describes two conditions. Firstly, apps must be easily available and accessible for people with diabetes and their HCPs. Secondly, apps should meet high standards of effectiveness and quality. The EUDF strongly suggests including people with diabetes and HCPs in all aspects and stages of the development and validation of apps, including empowerment and ensuring personalised, data-driven, user-friendly, easy to navigate, highly secure and interoperable apps, that provide relevant actionable data. Also, each member state should accelerate access to health apps based on harmonised EU requirements which include patient-reported outcomes. Moreover, apps that can prove real value should be reimbursed, integrated into healthcare pathways complementing direct personal care, and prescribed. With regard to evidence, different levels of evidence are advocated, depending on the function and relative medical risk of an app.

The European Society of Medical Oncology (ESMO) recently produced a clinical practice guideline for patient-reported outcome measures (PROM) including PROM software requirements [62]. Specified functionalities include a registration mechanism, the ability to trigger patients to report at specified time points, and a method for alerting clinicians when patient responses reach specified thresholds. Optional functionalities address the ability to provide educational materials or advice to patients on self-management, an open free-text box for patients to provide information not contained in the instrument, and (the technically challenging) integration with electronic medical record systems to enable data visualisation, storage, and management. Usability testing is required to ensure ease of use and comprehensible navigation for patients and providers, in particular for patients with limited health literacy. Access and affordability must be considered, and privacy and security assured, without making access overly cumbersome. A disclaimer that information entered in the system might not be rapidly reviewed by clinicians is often included to inform patients that they should call to seek emergency assistance for urgent problems.

The American Psychiatric Association (APA) has developed an app evaluation model to provide psychiatrists and patients with sufficient information to make an informed decision about apps [63]. This model includes five steps (access and background, privacy and security, clinical foundation, usability, and data integration towards therapeutic goal), each comprising from 5 to 9 questions. This app evaluation framework has been used by the New York Department of Health in the construction of an app library. The American Psychological Association has created the quarterly column for mental health professionals “Let’s Get Technical”, in which two experts review and rate software and apps [64] on seven criteria, including: purpose, appropriateness of the content, cultural responsiveness, ease of use, functionality, privacy/security, evidence base, and user feedback. Each expert also provides short directions for use.

3. What are the needs for correct mHealth use from the cardiology professionals' point of view?

A pivotal concern of HCPs for the guidance or prescription of mHealth applications is whether there is sufficient scientific evidence to support their intended use, in addition to their being technically robust, interoperable, secure, and private. Currently, there are no cardiology guidelines on such required levels of clinical evidence. The following section provides an overview of the current status and further needs for clinical evidence within the clinical domains of cardiac rhythm management, heart failure, and preventive cardiology.

3.a mHealth assessment and utilisation in rhythm management

Diagnostic support

The mHealth solutions designed to support cardiac rhythm management include tools for screening (also for underlying causes and mechanisms, such as sleep apnoea), triage, predicting risk, and detecting arrhythmias. Screening in this area has developed significantly in recent years and is focused mainly on atrial fibrillation (AF), and on the primary and secondary prevention of sudden cardiac death [65]. These mHealth solutions are predominantly used by HCPs and this field is expected to continue growing. Robust validation of these solutions is needed, as the performance of a solution may vary between different software versions, populations, and be limited by any differences between testing conditions and clinical practice where patients autonomously collect data [66-67]. For example, the sensitivity and specificity of reduced-lead ECG solutions vary significantly with disease prevalence [68]. A recent document from the European Heart Rhythm Association gives practical guidance and describes the level of consensus on the use of digital devices for the early detection, management and treatment of arrhythmias [69], as well as another expert collaborative statement [70] which defines the state-of-the-art mHealth technologies and their application in arrhythmia management and explores future directions for clinical applications.

An important consideration, besides the accuracy of the mHealth solution, is the actionability of its findings. For instance, NOAH-AFNET-6 showed that not all atrial high-rate episodes identify individuals that derive net benefit from anticoagulation. Studies have shown remarkable variation in practice in response to the same mHealth alerts [71]. These are important considerations as the development of new diagnostic tools may change the definition of conditions and thus prior practices may no longer be appropriate.

Other relevant requirements for the clinical evaluation of apps include improvement of clinical management, acceptability and usability of the solution, an increase in the diagnostic rate, and a reduction in morbidity and mortality. In addition, technical performance, cost and reimbursement will affect the take-up and use of a solution in everyday practice, so should therefore be considered [52].

Therapeutics

The therapeutic opportunities of mHealth in the field of arrhythmias are limited to indirect services because mHealth is based on a smartphone/tablet which cannot *per se* deliver any pharmacological or interventional therapy. Therefore, the therapeutic potential of mHealth is in the facilitation of treatment, which may be delivered via decision support, counselling, or alerting. Concerning decision support, the patient and/or physician may have some insight into the disease but want help to choose the 'best' treatment option. There are numerous mHealth solutions available such as Cardiosmart for AF from the American College of Cardiology [72], or the mAF app which provides more complex decision support [73]. In contrast, counselling involves more direct guidance for patients; mHealth has an important role to play in lifestyle modification and interventions, because it can improve patient motivation and understanding [74]. Finally, mHealth solutions capable of alerting HCPs, or the general public, could trigger lifesaving treatment in the case of cardiac arrest. For example, a trial in Sweden showed that a smartphone positioning system with the ability to dispatch lay volunteers trained in cardio-pulmonary resuscitation (CPR) was associated with increased rates of bystander-initiated CPR in patients with out-of-hospital cardiac arrest [75]. Also, mHealth could be a mediator of valid treatment strategies by improving understanding, adherence, concordance, and decision support. However, more clinical trials are needed to establish objective efficacy before the utilization of mHealth solutions can be incorporated in clinical guidelines as recommendation.

Remote follow-up

Remote follow-up provides an opportunity for increased recording of symptoms, and both invasive and non-invasive monitoring of physiological parameters. In this context, its main aims are to exclude potential pro-arrhythmic features and to assess the recurrence or development of new significant arrhythmias. Remote follow-up has been used for wearable devices, and cardiac implantable electronic devices (CIEDs - ECG loop recorders, pacemakers and defibrillators) for many years. More recently, wearables and other cardiac monitoring devices with built-in micro-detectors have been developed, which can provide real-time monitoring of vital signs [76-77]. These devices range from smart accessories to sensors embedded in accessories, clothing and even shoes and eyewear [78]. The majority have focused on heart rate monitoring and the detection of AF (see Diagnostic support). There are now "smartwear" devices which can identify pro-arrhythmic features such as QT prolongation, ventricular arrhythmias, or the Brugada ECG pattern [79-80]. These are becoming increasingly affordable and bring the advantage of continuous monitoring, but their accuracy and reliability vary greatly. Most wearable devices have an evidence base, but many are associated with a significant false-positive rate. In addition, some are limited by the complexity of the user interface and/or dependence on the manufacturer for access to data.

Education

Both for patients and HCPs, education supported by technology (eHealth, mHealth, and clinical decision support tools) is a core component of integrated care for AF [81]. The primary goal of digital education is to improve patients' health literacy, engagement and empowerment in self-management (e.g. adherence to medication, behavioural and lifestyle changes). For HCPs, digital education solutions are typically designed as clinical decision-support tools. Examples of apps for AF which have been, or are being, formally tested, include a patient-version of the mobile AF app (mAFA) designed to promote engagement [82], the HCP mAF app for clinical decision-support in stroke and bleeding risk stratification, and the mAF App for improving knowledge and medication adherence [73]. More recently, the mAFA II app-supported Atrial Fibrillation Better Care (ABC pathway) significantly reduced the composite primary outcome of ischaemic stroke, thrombo-embolism, death and re-hospitalisation, compared to usual care [83]. The ESC has also developed apps for AF patients ('MyAF') and HCPs ('AF Manager') [65]. The patient-version is currently being tested prospectively in the STEEER-AF randomised controlled trial [84]. During the pandemic, an on-demand app-based heart rate and rhythm monitoring approach to manage AF patients via teleconsultation (TeleCheck-AF) was developed and implemented, incorporating (1) a structured 'teleconsultation'; (2) a mobile phone app (FibriCheck) using photoplethysmography to monitor rate and rhythm; and (3) a comprehensive AF management plan including patient education [85-86]. Exploration of the patient experience of TeleCheck-AF (n=826) found that 94% felt it was easy to use, and 74% 'felt safer' when being monitored [87]. More research is required on the design and implementation of digital education solutions in cardiac rhythm management and their effects on health literacy and patient actions.

3.b mHealth assessment and utilization in heart failure

Diagnostic support

mHealth apps may be useful as diagnostic tools for screening, triage, assessment of severity, and the diagnosis of heart failure (HF). Whereas algorithms have been developed that may be useful in this regard [88,89], no application is currently available for clinical use. To add value in clinical practice, mHealth apps need to be at least as accurate as current standards (e.g. natriuretic peptides for screening or exclusion of HF; echocardiography) [90] or show a better or more efficient process in the diagnosis of HF (e.g. pre-selection of patients to undergo further examination such as echocardiography, resulting in fewer unnecessary referrals and reducing costs) in a sufficiently powered clinical study. Other mHealth applications focus on risk prediction and assessment of the severity of HF. These are helpful only when their clinical significance is clearly defined [91], which is not the case for most currently available risk predictors (e.g. risk scores). To be approved, an mHealth tool for risk prediction or assessment of HF severity must have been shown to have resulted in therapeutic intervention(s) that prevented deterioration and/or improved outcomes in an appropriately designed trial. In addition, mHealth apps should also aid the diagnosis of common co-morbidities in HF [92] that contribute to both morbidity and mortality, or may require specific therapeutic interventions.

Therapeutics

The mHealth apps may directly initiate a therapeutic intervention (e.g. medication for diabetes – but currently there are no equivalent examples in HF) or they may modify therapeutic interventions in patients with HF (e.g. adjustment of diuretic therapy or up-titration of medication) [93]. Additionally, they may include interventions related to lifestyle (e.g. reducing salt intake, monitoring physical activity/exercise), and self-management (e.g. adherence to medication, monitoring of congestion or treatment side effects). There have been many mHealth studies on lifestyle and self-care [94], but important challenges remain because of the heterogeneity of approaches being tested, limitations in study designs, small sample sizes, and the potential impact of the healthcare system on the effects: as a result, the evidence of efficacy is limited [95]. Taking into account the advanced age of many patients affected by HF, their associated comorbidities and frequent re-hospitalisation, the lack of digital literacy may in some settings constitute a limitation for using wearables and apps in a large number of older patients [96].

Remote follow-up

Remote monitoring (RM) is among the most promising strategies for patients with HF in the out-patient setting [97]. RM technologies can transmit patient-obtained weight and vital signs or more advanced physiological measurements such as thoracic impedance and intracardiac pressures [98]. Trials evaluating the clinical effects of non-invasive remote assessment of vital signs have shown conflicting results. Whereas the SUPPORT-HF2 and BEAT-HF studies showed negative results [99, 100], TIM-HF2 [101] showed high adherence (97% of patients were 70% compliant with daily data transfer) and clinical superiority of a non-invasive multicomponent telemonitoring home system with daily wireless transmission, versus usual care.

Examples of wearables currently used in HF patients are patches, clothing monitors, chest straps, upper arm bands, and medical wristbands [102]. Thoracic impedance has not emerged as an important RM tool, probably due to its low sensitivity, measured at approximately 30% for clinically adjudicated pulmonary congestion in two studies [103-104]. Although it requires the use of a wearable device, a novel technology called ReDS™, based on tissue dielectric properties, seems more promising with a 50% reduction in HF readmission [105]. Invasive RM technologies include implantable intracardiac devices which directly measure cardiac pressures. One of the most widely studied devices is CardioMEMS, a pulmonary artery pressure monitor, which has shown a clinically significant reduction in HF hospitalisation [106] with high adherence [107]. In contrast, left atrial pressure transducers have not yet demonstrated clinical benefit [108], and reliable non-invasive alternatives for the early detection of deterioration are still lacking.

The ability of RM of CIEDs in the prevention of disease progression and to improve outcomes in patients with HF is still controversial. Currents CIED provide diagnostic information through mobile transmitters to monitor for arrhythmias and HF decompensation, creating opportunities for early intervention prior to deterioration and hospitalization. Continuous connectivity and prompt and structured reaction to alerts may be key to improving CIED patient outcomes [109].

Education

Patient education in HF is directed at improving understanding and self-care and is supported by meta-analysis [110], and current ESC guidelines [90]. Patients who report effective self-care have measurably improved quality of life, lower readmission rates, and reduced mortality. Patient educational materials may cover disease trajectory, understanding of medications, device therapy, and lifestyle interventions to improve self-care including exercise, diet, symptom monitoring, self-management and the psychological effects of heart failure. HCPs can provide educational materials in a variety of formats to suit individual patients' needs and health literacy. These include paper or digital booklets [111], websites [112], or apps, and may use text, links to on-line material, videos, virtual or augmented reality experiences, and interactive robots providing advice as an eCoach. High-quality apps include accurate information, which is consistent with best practice, as defined by current guidelines. Furthermore, they have been demonstrated to improve patients' knowledge and clinical outcomes in high-quality controlled trials. Recently, specific apps have been developed to empower patients carrying a cardiac electronic device that is linked with RM, in order to improve their adherence to the recommended care pathway, and to obtain quick feedback on their health status [113].

3.c mHealth assessment and utilisation in preventive cardiology

Diagnostic support

In primary and secondary prevention programmes, mHealth systems have been shown to be effective for screening, diagnosis, and risk stratification [39, 114]. In primary prevention, there is an increasing number of apps for the detection of arterial hypertension, cholesterol levels and lifestyle monitoring including diet, weight and exercise [115-118], many of which have not been certified as MD software. Also, there are several apps for secondary prevention in patients with HF, a history of myocardial infarction or valvular heart disease [119-23]. The ESC has developed a CVD Risk Calculation App for HCPs [124] which guides clinicians to the most appropriate of the 8 calculators available for 10-year or life-long risk assessment for primary or secondary prevention CV patients. Unfortunately, most of the available apps lack scientific validation of their ability to detect increased CV risk accurately or reliably predict outcomes, as the available data are from small studies. In addition, it remains to be determined whether clinical decision-making based on risk prediction improves outcomes.

Therapeutics

Therapeutic goals that can be pursued successfully by mHealth applications for primary and secondary prevention purposes include lifestyle management, improving self-management skills, the assessment of medication (side)effects, and adherence to treatment [125]. Additionally, for secondary prevention, tele-rehabilitation is an emerging field of interest, showing at least equal efficacy to traditional centre-based cardiac rehabilitation programmes [126]. Although digital lifestyle (self-) management applications (e.g. smoking cessation, exercise coaching, nutritional guidance; and management of mental disorders, anxiety and depression) are widely available and potentially effective in the short-term, their long-term effects remain uncertain. Evidence of the effectiveness of apps for improving medication adherence, prescription and assessment of effects is emerging. Characteristics contributing to the effects on usability and effectiveness of these apps are not well established, but essential for the development of more effective applications [122].

Remote follow-up

Remote follow-up and telemonitoring are becoming increasingly popular for primary and secondary prevention. This technology allows closer follow-up of the evolution of CV risk factors and quicker intervention when specific prevention goals are not achieved. Furthermore, telemonitoring may reduce the number of outpatient clinic visits and healthcare costs [127]. Different forms of telemonitoring in primary and secondary prevention already exist (e.g. for arterial hypertension, diabetes mellitus, physical activity, and weight) and new wearables and biosensors are emerging rapidly [125,128]. Telemonitoring in primary prevention should be focused mainly on self-management and patient empowerment, with low input of HCPs to minimise costs.

Education

Education of the patient is one of the core components of CV prevention and rehabilitation [129], with documented effects on CV events and quality of life [130] through changes in lifestyle and behaviour which can reduce risk factors. The main advantage of the remote, digital delivery of education, is that it can be tailored to an individual's needs, divided into appropriate sections, and delivered and repeated at appropriate times for the patient. Digital education may include infographics, standard and virtual reality videos, forums and a digital Nurse/eCoach. These applications can be used alone or as an integral part of a tele-rehabilitation platform [125]. It has been shown that educational interventions in chronic disease improve biological outcomes, adherence to the treatment regimen, knowledge, self-efficacy and psychological health, but more research is needed on the most effective timing and delivery of digital education to change behaviour and lifestyle [131].

4. Factors to consider before suggesting the use of mHealth solutions

There are currently multiple national initiatives reviewing mHealth applications (see section 2a). Therefore, in order to select an appropriate mHealth solution, it may be helpful to review these curated libraries regularly, although it should be acknowledged that the requirements and rigor of the initial assessment and follow-up assessment framework may vary significantly between libraries.

It is increasingly recognised that the recently developed CEN-ISO/TS 82304-2 health app assessment framework, once implemented and available, has the potential to be a widely used, efficient, international quality assessment framework for mHealth [132], supported by the Standing Committee of European Doctors (CPME) [133]. The CEN-ISO/TS 82304-2 health app quality label and report could help drive decision-making in the selection of a specific solution. Moreover, the four overarching quality metrics in the 82304-2 label mirror the quality requirements listed in Annex II of the recently published European Health Data Space Regulation draft [134], which includes the labelling of wellness apps that aim to be interoperable with Electronic Health Record systems, a cascading effect in MD, and an EU database where labelled applications will be registered.

Different contexts and patient characteristics, including age, gender, educational level, cultural diversity, learning styles, health literacy, engagement techniques and diagnosis, may result in certain quality requirements in the CEN-ISO/TS 82304-2 label and report that will be particularly important for individual patients. This Taskforce would like to stress the importance of two requirements in particular: 1) co-development with relevant stakeholders (i.e. patients, family, caregivers, those with low health literacy, and HCPs, for all categories; and specific stakeholders, such as primary care, the scientific community, and regulatory authorities) to enhance patient acceptability and usability (82304-2 requirement 5.3.2.2); and 2) the need to build in maintenance of the health information in the app (82304-2 requirement 5.2.4.6) to ensure that it remains evidence-based and consistent with contemporary best practice.

The availability of mHealth solutions for patients relies on the complex relationship between private sector investors, regulators, private and public payers, telecommunications providers, and end users. It must be noted that there are no legal obligations for the investors to focus on cost-effectiveness, health outcomes or sustainability. Assessment frameworks, such as CEN-ISO/TS 82304-2:2021 [56] and HTA methods developed for digital products [58], include information on costs for the end-users. Some also require accurate information on the details of all costs, including costs for the organization as well as the end-users, and on the maintenance cost and the uncertainty factors associated with these costs. A recent initiative in this context is represented by the European Taskforce for Harmonised Evaluation of Digital Medical Devices, established in April 2022 under the

French Presidency of the Council of the EU and consisting of 20 representatives of different European public and academic institutions, including HTA bodies, chaired by the Ministerial Digital Health delegation of the French Ministry of Health and Prevention, co-chaired by the European Network for Health Technology Assessment (EUnetHTA) and co-ordinated by EIT Health. Its goal is harmonisation of the evaluation procedures for patient-centred Digital Medical Devices (DMDs) in the EU, supporting national appraisal and reimbursement [135].

Although the potential added economic value of mHealth solutions is predicted to be very high, with estimates of €99 billion in 2017, data on the extra but potentially also reduced workforce costs to support mHealth and its actual economic impact are scarce, and those that exist come predominantly from high and middle income countries [136]. In a recent systematic review of the cost-effectiveness of digital health interventions in the management of CV diseases, 6 of the 14 interventions were cost saving while the remaining 8 had a higher, although acceptable, incremental cost-effectiveness ratios. In addition, only two thirds of the studies were classified as good quality [137]. In another cost-effectiveness review of mHealth interventions for older adults (multiple indications, including CV) no evidence of cost-effectiveness for "interventions related to complex smartphone communication" was found [138]. Overall, the evidence is reassuring for high income countries, but the potential value added by mHealth in low-resource settings is less certain, especially as digital health solutions should not be considered in isolation, but in the context of the overall infrastructure of healthcare systems and the complexity of healthcare delivery [139]. On the other hand, mHealth solutions have a high potential in low-income countries where aspects such as monitoring of arrhythmias, HF or prevention are less well developed clinically. The design of an mHealth solution for a low resource country should rely more on "semi-automatic" responses, minimising human intervention.

It has to be considered that the approach to costs for mHealth solutions could also include new approaches, such as risk-sharing agreements, characterized by linking coverage, reimbursement, or payment for an innovative technology, such as some mHealth applications, to the attainment of pre-specified clinical outcomes [140]. In this perspective, Scientific Associations may have an important role in promoting the basis for this type of value-based assessments.

5. Clinical consensus statement on assessment of clinical evidence for the appropriate use of mHealth

A series of indications for the assessment of clinical evidence required for the appropriate use of mHealth applications in the field of cardiology is presented below, derived from the available literature combined with expert opinion. These statements were formulated by consensus of experts in a range of cardiology domains (at least 5 per domain) invited by the Regulatory Affairs Committee and ESC Associations in this mHealth Taskforce. The consensus process consisted of 2 workshops, during which alignment among the participants on the topic of clinical evaluation of software and the changes introduced by the EU Medical Device Regulation was reached, and the proposed goals of the task force were set and clarified. In addition, the composition of the three sub-groups (Rhythm management, Heart failure and Preventive Cardiology) and the appointment of a sub-group coordinator was finalized. After an online questionnaire exploring the perceived trust in recommending mHealth solutions, including positive and negative examples encountered in their practice, each subgroup was asked to discuss and reach a consensus in separate meetings on clinical efficacy and related criteria that could be considered important for the respective clinical scenario (now indicated in Table 1, or as general criteria). In addition, a live survey and discussion was conducted to explore the ISO 82304-2 quality requirements in relation to the possible application of such a scheme in the evaluation of the level of clinical evidence.

The resulting statements are intended to aid cardiology HCPs in the selection of an appropriate mHealth application for a specific purpose, or to evaluate whether information generated by a patient app should be used for clinical decision-making. In addition, they may be taken into account by NB in the certification of Class IIa and higher risk MD, and also by ISO/TS 82304-2 certification bodies once they will be established.

5.a General criteria for the assessment of clinical evidence

- Evaluate whether evidence was generated in the appropriate (i.e. subjects with similar profile to those intended as final users) sufficiently described patient-population (e.g. based on age, gender, educational level, health literacy, CV risk profile, exercise capacity)

- Carefully review the intended use and relevant claims of the manufacturer, as well as declared operating ranges and exclusion criteria
- Consider whether clinical validation was performed using appropriate standards for the intended use (e.g. 12-lead ECG for the diagnosis of AF)
- Check nominal performance and whether this is affected by software updates
- Evaluate whether conclusions were drawn from sufficiently powered studies based on meaningful clinical effects in the primary end point
- Evaluate whether the duration of longitudinal studies was sufficient to assess the treatment effects under evaluation
- Evaluate the potential impact on the implementation in clinical pathways, by considering the sustainability for the specific healthcare system in terms of expected increase in workload and reimbursement for related medical services, in particular when HCP surveillance is required
- Apps that show or are tested for non-inferiority should provide evidence of an additional benefit, such as earlier correct decision making, a reduction in resource use, improved cost-effectiveness, or cost-saving.

5.b Domain-specific criteria for the assessment of clinical evidence

In addition to the general criteria, more specific requirements are advised for each of the clinical domains in which mHealth solutions are most frequently used (i.e. rhythm management, HF, and preventive cardiology). These are presented in Table 1, divided according to the intended use (i.e. diagnosis, therapeutics and remote follow-up), as different approaches may be required for each clinical domain. These criteria, without claiming to be an exhaustive list, stress the importance of the HCP in verifying, using easily accessible sources (i.e., literature search websites, manufacturer documentation or website, currently available assessment schemes) the level of clinical evidence available in order to trust a specific mHealth solution.

Table 1. Advised criteria for the assessment of clinical evidence needed for the use of mHealth applications in clinical practice

	Rhythm management	**Heart Failure**	**Preventive Cardiology**
Diagnostic support	Increased (at least non-inferior) diagnostic rates should be demonstrated, compared with standard care Performance should be interpreted with care if reported only in controlled scenarios, because of possible differences to real-life performance. Specificity and sensitivity compared to the gold standard should be interpreted with respect to the prevalence of the disease in the assessed population.	Diagnosis of HF or comorbidities: Increased (at least non-inferior) diagnostic rates should be demonstrated, compared with standard care, preferably together with positive effects on the efficiency of the process in diagnosing HF. Risk prediction scores retrospectively and prospectively validated in real-world settings should be used, and their clinical implications should be determined.	Accuracy in the assessment of risk factors and lifestyle behaviour should be reported. Risk prediction scores retrospectively and prospectively validated in real-world settings should be used, and their clinical implications should be determined.
Therapeutics	Solutions incorporating clinical decision-support tools: superiority with respect to at least one clinically important factor (e.g. reduction in clinical events, improvement in patient reported outcomes) or non-inferiority with reduction in related costs should be demonstrated in a prospective randomized controlled trial. Lifestyle behavioural interventions: see preventive cardiology.	Solutions incorporating clinical decision-support tools directly related to therapy (e.g. adjustment of medication): superiority with respect to at least one clinically important factor (e.g. reduction in clinical events, improvement in patient reported outcomes) or non-inferiority with reduction in related costs should be demonstrated in a prospective randomised controlled trial. Lifestyle behavioural interventions: see preventive cardiology.	Lifestyle behaviour, risk factor treatment, medication adherence (in primary and secondary prevention), safety and efficacy in derivate outcomes (e.g. short-term compliance and clinical effects) should be positively evaluated. Solutions for tele-rehabilitation: non-inferiority compared to conventional rehabilitation in clinical outcomes (CV risk, events or re-vascularisation, quality of life) should be demonstrated. Applications that can also provide evidence of long-term outcomes should be preferred. The presence of behavioural models and relevant strategies for behavioural change should be addressed. The possibility of tailoring the solution to specific patients'

			needs and preferences should be considered as positive factor for improved engagement.
Remote follow-up	Increased (at least non-inferior) diagnostic rates should be demonstrated, compared to standard care Performance should be interpreted with care if reported only in controlled scenarios, because of possible differences to real-life performance. Specificity and sensitivity compared to the gold standard should be interpreted with respect to the prevalence of the disease in the assessed population.	Superiority with respect to at least one clinically important factor (hospitalisation, cost-effectiveness, or improvement in patient reported outcome) should be demonstrated in a prospective randomized controlled trial. Decision support: added value in the treatment process (e.g. more or faster up titration to optimal medical therapy, reduction in costs) should be demonstrated	Lifestyle behaviour, risk factor modification, medication adherence (in primary and secondary prevention), safety and efficacy in derived outcomes (e.g. short-term compliance and clinical effects) should be positively evaluated. Solutions for tele-rehabilitation: non-inferiority compared to conventional rehabilitation in clinical outcomes (CV risk, events or re-vascularization, quality of life) should be demonstrated. Applications that can also provide evidence of long-term outcomes should be preferred. The presence of behavioural models and relevant strategies for behavioural change should be addressed. The possibility of tailoring the solution to specific patients' needs and preferences should be considered as positive factor for improved engagement.
Education	The effectiveness of educational interventions, including improved health literacy, and patient actions towards a behavioural and lifestyle change, should be quantitatively evaluated. These aspects should be assessed using validated scales at baseline compared to the end-of-intervention period, as a minimum. Further evaluation could include persistence in the longer term, after the official end of the intervention, as well as comparison to the standard of care. Information on frequency of updating of the information should be reported.		

Examples or case studies demonstrating possible practical application of the proposed general and specific criteria are reported in Supplementary material Table A.

The proposed criteria, both general and specific, represent possible aspects that the clinician could take into consideration to evaluate the level of clinical evidence associated to a certain mHealth solution, by examining different sources of information (e.g. existing publications, manufacturer's claims through its website, public or private assessment schemes). To facilitate this process, the recently developed CEN-ISO/TS 82304-2 health app quality assessment framework, once applied and operative, would result in a label (created by a conformity assessment and certification body based on the replies of the manufacturer to 81 questions and related evidence) summarizing the app's benefits in several domains (Healthy and safe, Easy to use, Secure data, Robust build) as well as an overall health app quality score, ready-to-be-used by the clinician. As reported in the Supplementary material Table B, all of the criteria suggested in this article could be mapped to the quality requirements of the CEN-ISO/TS 82304-2, so that the label and related report, once available, could facilitate the evaluation by the HCP.

6. Conclusions

Mobile health solutions have the potential to enable cardiac patients to take a more active role in their own care and to improve contemporary clinical care pathways. To reduce existing barriers that prevent such utilization, and to guide HCPs in the evaluation of the level of available evidence for mHealth solutions, both general and specific criteria were formulated as consensus by a Task Force initiated within the ESC Regulatory Affairs Committee. The Task Force included clinical experts, patient representatives and members with recent experience of working in a NB; existing assessment frameworks and initiatives of other medical associations were also taken into account.

Rhythm management, heart failure, and preventive cardiology were chosen as specific fields in CV clinical practice in which mHealth solutions are potentially useful for patients, and these were divided by their intended uses (i.e. diagnostic support, therapeutics, remote follow-up and education). After providing a definition of the problem informed by the views of stakeholders, possible ways to obtain information about the level of evidence were presented. The analysis of HCP's needs for a correct use of mHealth in these three fields allowed the definition of particular factors to be considered when suggesting the use of mHealth solutions to patients. Consensus was reached on both the general and specific guidance for the assessment of clinical evidence and the need for standardised regulatory criteria and processes.

We are aware that this work does not cover all possible usage of mHealth, but we are confident that our approach, focused on exploring specific needs according to their intended uses, could facilitate further work exploring and extending it to other CV clinical domains, thus avoiding a "one-size-fits-all" strategy.

This ESC clinical consensus statement recognizes the need for input from professional medical associations and scientific societies to support professionals in the use of mHealth in clinical practice. It is intended to make them aware of the national approval programs for mHealth solutions that have fulfilled the required criteria for their sustainable introduction into clinical practice, and support trust development among professionals that are unsure of prescribing mHealth solutions [54,141].

Defining these proposed criteria represents a first step to make the other stakeholders (manufacturers, notified bodies, and national regulatory authorities) aware of the ESC community's opinion of the level of clinical evidence required for the recommendation of mHealth solutions, and to underline how the recently developed CEN-ISO/TS 82304-2 health app quality assessment framework could support these needs, without additional burden for the HCP. It is now the role of regulators and policy makers to consider this consensus statement, and create a pathway for either this or similar frameworks to be put into effect.

Declarations

Conflict of Interest

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Data availability

There are no new data associated with this article.

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