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REVIEW

Wearables, telemedicine, and artificial intelligence in arrhythmias and heart failure: Proceedings of the European Society of Cardiology Cardiovascular Round Table

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Abstract

Digital technology is now an integral part of medicine. Tools for detecting, screening, diagnosis, and monitoring health-related parameters have improved patient care and enabled individuals to identify issues leading to better management of their own health. Wearable technologies have integrated sensors and can measure physical activity, heart rate and rhythm, and glucose and electrolytes. For individuals at risk, wearables or other devices may be useful for early detection of atrial fibrillation or sub-clinical states of cardiovascular disease, disease management of cardiovascular diseases such as hypertension and heart failure, and lifestyle modification. Health data are available from a multitude of sources, namely clinical, laboratory and imaging data, genetic profiles, wearables, implantable devices, patient-generated measurements, and social and environmental data. Artificial intelligence is needed to efficiently extract value from this constantly increasing volume and variety of data and to help in its interpretation. Indeed, it is not the acquisition of digital information, but rather the smart handling and analysis that is challenging. There are multiple stakeholder groups involved in the development and effective implementation of digital tools. While the needs of these groups may vary, they also have many commonalities, including the following: a desire for data privacy and security; the need for understandable, trustworthy, and transparent systems; standardized processes for regulatory and reimbursement assessments; and better ways of rapidly assessing value.

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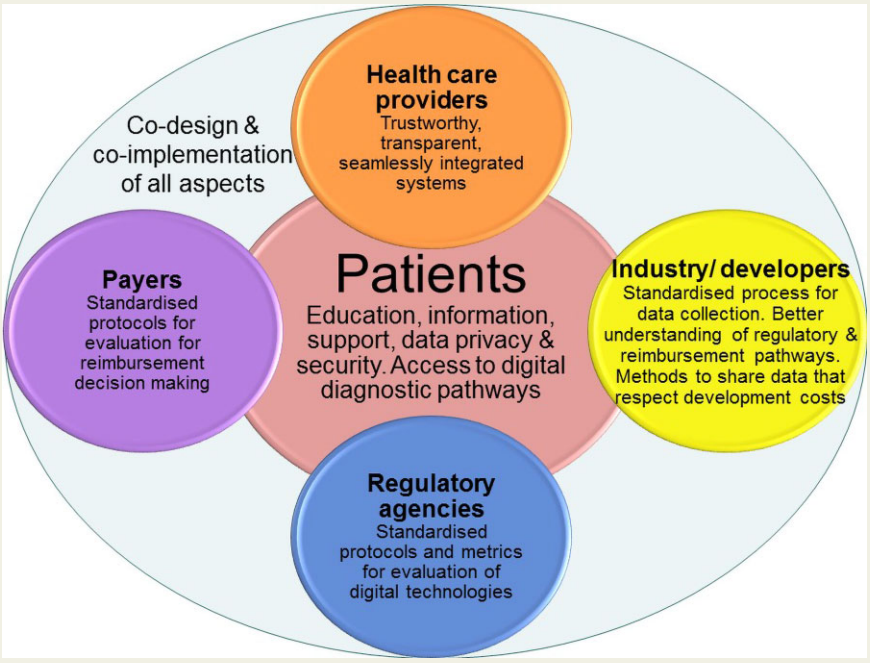
Graphical Abstract



Fundamental needs of stakeholders involved in digital healthcare.

Keywords M-health • Wearable devices • Monitoring • Early detection • Digital healthcare solutions • Artificial intelligence

Introduction

There is no question that digital technology has changed the world in which we live. In medicine, tools for detecting, screening, diagnosis, and monitoring have improved patient care, but one of the biggest changes is the ability of individuals to use technology to better manage their own health and lifestyle. There has been an evolution of thinking from closed systems (top down) to open networks (interconnected).[1,2] This may be especially true in healthcare where patients have, in general, become increasingly active participants in maintaining and improving their own health. The doctor–patient relationship is moving away from a hierarchical, institutionalized system, to one of collaboration and shared decision-making. Patients can obtain health information and guidance from a potentially bewildering array of sources including websites, health records, online patient communities including social media, self-monitoring devices, and health-related applications using smart devices (m-Health), and not just from traditional healthcare systems or healthcare professionals (HCPs). The benefits are potentially enormous but require active participation and communication between patients and their HCPs, as well as flexibility, transparency, trust, and a well-defined reimbursement system.[2]

Patients are becoming digital partners; sometimes called 'ePatients', individuals are self-detecting, self-diagnosing, self-managing, and increasingly expecting to share in decision-making.[3,4] Mobile health technologies have facilitated patient self-care of chronic and lifestyle-related diseases.[5] Moreover, in a few years, self-diagnostic centres may widely replace traditional diagnostic infrastructure. However, issues of data collection, storage, and access, including privacy and confidentiality (real or perceived) continue to cause concerns.[6,7] Furthermore, the complexity of data and information from different sources requires a deep understanding, with education for patients as well as HCPs. The HCP is essential for the interpretation of the data and the evaluation of the potential risk and harm of any therapeutic decision for an individual patient. Lack of knowledge, limited access to healthcare, and limited access to consumer wearables due to relatively high costs, can lead to health inequalities.

The COVID-19 pandemic substantially accelerated the use of digital technology.[8,9] For example, in a survey of European electrophysiologists, 65% said that they had initiated new remote monitoring connections for cardiovascular (CV) devices implanted before the pandemic.[10] In addition, data for England showed that teleconsultations more than doubled from around 850 000 to >2 million/week during the early months of the pandemic.[11] Similarly, in France, at their peak, teleconsultations accounted for about 27% of consultations, and while there was subsequently a slowdown, data suggest they are likely to remain higher than before the pandemic.[11] Inadequate infrastructure, support, and probably most importantly inadequate reimbursement are ongoing barriers to realizing the enormous potential of these new technologies to improve patient clinical outcomes and experience of care.[8–10]

Digital technologies are already an essential part of healthcare management, and the area is constantly expanding and changing.

The healthcare system needs to ensure adequate education and support for all stakeholders. The evidence-based use of digital technologies should be part of guideline recommendations, and regulatory bodies must accelerate the development of clear standards for assessment and guidance for use.

This article is the product of presentations and discussions during a virtual Cardiovascular Round Table (CRT) workshop organized in October 2021 by the European Society of Cardiology (ESC). It aims to explore the benefits and challenges associated with digital healthcare solutions from multiple stakeholder perspectives, including: patients, HCPs, pharmaceutical and device manufacturers, consumer device companies, technology solution companies, hospital administrators, healthcare systems specialists, regulatory bodies, and scientific societies.

Digital solutions for arrhythmias and heart failure

The terminology used in the context of digital health continues to evolve. It includes internet-based education training and education, remote monitoring, telemedicine, and m-Health (i.e. wearable consumer-type devices and smartphone applications).[6,12,13] Remote monitoring generally involves the transmission of patient data to clinicians, followed by telephone or internet-based patient-clinician interaction based on pre-specified alert thresholds and rarely an outpatient visit.[12,14] Digital health also involves collecting, sharing, and interpreting health data to detect patterns and develop strategies to improve individual and collective patient health outcomes.[15,16]

Smart wearable devices and their cardiovascular applications

Wearable devices use a variety of sensors, such as accelerometers, barometers, electrocardiographs, oscillometers, and photoplethysmographs. *Figure 1* shows a summary of some of the smart devices that are worn on the body, the types of sensors, and the measurements that can be obtained.[6,17,18]

Demonstrated utility in arrhythmias and heart failure

The use of devices such as cardiovascular implantable electronic devices (CIEDs) with remote monitoring has demonstrated benefits in the area of arrhythmias, including reductions in office/hospital visits[19–21] and inappropriate shocks;[22] earlier detection of device malfunction;[23] and reduced time to clinical decisions.[22,24] Safety has been demonstrated, with no increased risk of major adverse cardiac event,[25] and in fact, some studies report a potential reduction in mortality.[21,22] A meta-analysis of 12 studies found a relative risk of stroke of 0.513 (95% CI, 0.265–0.996) in patients with CIEDs, but no difference in the rate of detection of AF.[26] Some studies show that for those who are at risk for arrhythmias, wearables or other devices and remote monitoring can be useful for the early detection of AF, and other CV diseases.[27–30] The 2021 ESC guidelines on cardiac pacing and cardiac resynchronization therapy recommend remote monitoring of pacemakers to reduce the number of in-office follow-up visits (one in-person visit every 2 years), and that it should be considered for early detection of clinical problems or device technical issues and can be useful for the management of recalls.[31]

The 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure (HF) recommend a CIED for subgroups of patients with symptomatic HF, and those with arrhythmias.[32] However, the guidelines concluded that while remote monitoring of devices is useful for early detection of device malfunction; there was limited evidence for reductions in HF hospitalization or mortality. Meta-analyses of trials of remote monitoring for implantable devices have concluded that overall there was no significant impact on all-cause mortality or HF hospitalizations, but that remote monitoring of pulmonary pressure may reduce the risk of HF hospitalizations.[33–35] This was largely based on the results of the CHAMPION trial.[36,37] Those findings were recently partially supported by the results of the larger GUIDE-HF trial, which found a significant benefit on the incidence of all-cause mortality or HF events in the intervention group in a pre-specified pre-COVID-19 impact analysis.[38] The overall results were not significant.

The ESC guidelines recommended that non-invasive home telemonitoring may be considered for patients with HF, to reduce recurrent CV and HF hospitalizations, and CV death[32] This is supported by meta-analyses published before the guidelines,[39,40] and a more recent analysis.[41] The guidelines state that if social distancing and the 'green' agenda are important, remote monitoring becomes appropriate as long as it is not inferior to standard delivery of care. However, there was insufficient evidence to determine whether wearable technologies offer benefits over telemonitoring alone.[32]

Artificial intelligence in cardiology

Health data are now coming from a multitude of sources such as clinical, laboratory and imaging data, genetic profiles, wearable technology, implantable devices and sensors, patient-generated measurements, medical claims data, social data, and environmental data (*Figure 2*).[42,43] Such 'Big Data' are often characterized as of high volume, velocity, variety, value, and (arguably) veracity.

Artificial intelligence (AI) refers to the use of algorithms and software that demonstrate human-like cognition in analysing, interpreting, and understanding complicated data.[43] Machine learning (ML) including deep learning and neural networks, is a subset of AI, where machines extract information from data. Algorithms must be trained to process information. They may then have the potential to increase the usefulness of the constantly increasing volume and variety of longitudinal data. This may help HCPs to interpret the findings more accurately, thus supporting better-shared decision-making and outcomes, and experiences of care,[42] although, it is important to underline the need for strong external validation. Artificial intelligence algorithms have been developed to decrease false-positive alerts during AF monitoring,[44,45] find patterns to detect patients at risk,[46] and to better predict HF hospitalization.[47]

Perspectives of individuals with health conditions/risks

As discussed above, individuals living with long-term conditions may directly benefit from remote monitoring of CIEDs, and the use of

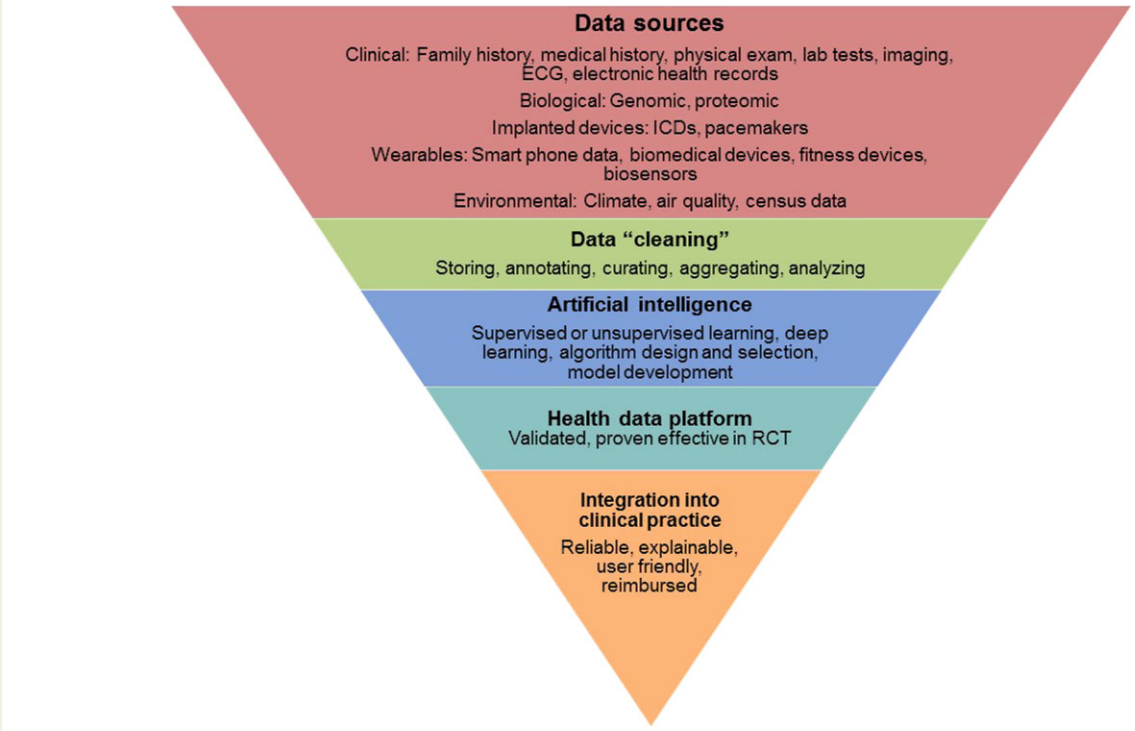


Figure 1 Summary of some of the types of smart wearable devices, where they are worn, sensors, and measurement. Based on references.[6,17,18] This is not an inclusive list. Photoplethysmography (PPG) measures HR, HRR, HRV, cuff-less BP, SaO_2, cardiac output, stroke volume, pulse-based rhythm detection, and sleep and its stages. BP, blood pressure; ECG, electrocardiogram; GPS, Global Positioning System; HR, heart rate; HRR, heart rate recovery; HRV, heart rate variability; PPG, photoplethysmography; SaO_2, oxygen saturation.

wearables or other devices for the early detection of AF and CV events, and to monitor the progression or stability of HF.[19–24,27–29] Digital technologies have enabled individuals to take an active part in their healthcare, particularly for chronic and risk factor-related diseases.[5]

It is important that the devices/tools are clinically validated. However, patients (and often HCPs) may not always be aware that some mobile tools have undergone clinical evaluation and regulatory approval (e.g. see www.knowyourpulse.org or www.cta.tech for more information about digital tools for the detection of AF).

In a 2021 AF Association survey of 508 people, 79% responded that they would want to use mobile electrocardiogram (ECG) tools to detect AF (www.heartrhythmalliance.org). Individuals ($n = 159$) endorsed the following benefits of remote monitoring: fewer trips to the hospital, being involved in their own care, reassurance/peace of mind, more consistent follow-up, and less time commitment. A programme assessing remote app-based management of AF found that most patients (74%) reported a feeling of safety because of the constant control of heart rate and rhythm, and almost two-third wanted to continue using the programme in the future.[48] This quality-of-life benefit for patients may not always be captured by traditional trial outcomes.

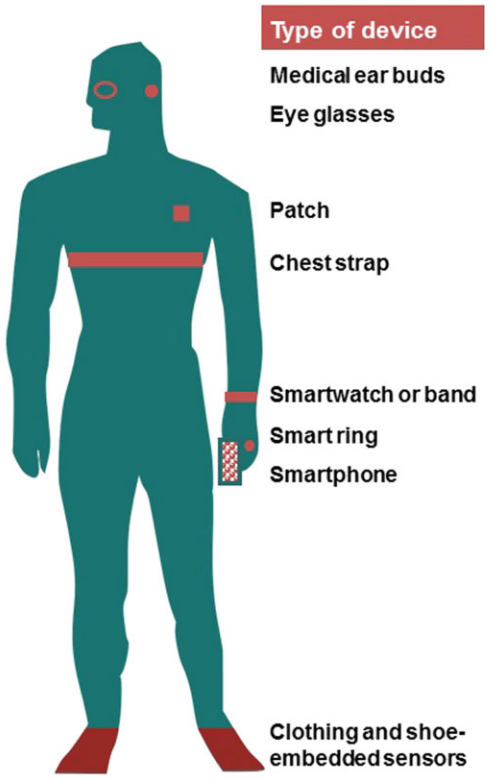
In a large US general population survey, the top reasons people used wearable technologies involved improving healthy behaviours (e.g. exercise, weight loss, sleep, and stress).[7] In addition, in 2020 more respondents stated that they used their wearable to 'manage a diagnosed condition', from 28% in a 2019 survey to 51% in 2020, which was likely related to the COVID-19 pandemic. While the survey required digital access, the demographics revealed that the survey population closely matched US census demographics in age, sex, income, and ethnicity.

Challenges

While most patients would like to use mobile ECG tools and remote monitoring, some do not want to, and these patients should have equal opportunities to have their healthcare needs assessed.[6,7,49–51] Some patients do not have the digital or health literacy, the economic resources, access to digital tools related to regional disparities, or the desire to use digital technologies (*Table 1*).[6,7]

Although some patients perceived easier access to healthcare, others had concerns around privacy, or the need for in-person physical examinations.[52,53] Technological issues are a frequent problem with video visits.[52,53] Patients were more likely to be satisfied with telehealth if they had reliable internet access and higher health literacy.[54] In addition, patients were more likely to use telemedicine if they had one or more chronic conditions (78 vs. 56% without a chronic condition, $P < 0.001$).[7] Preparing and supporting those using digital technology (whether a patient or a HCP) is essential.[55]

There are also concerns around data collection, storage, governance, and access.[6,7] In a US survey, most individuals were willing to share their health data with their doctor (72%), but fewer with their health insurer (53%) or family (52%). Among individuals with digital trackers, two-thirds were willing to share data with their physician, but only about one-third would share with research institutions,



Sensors	Measurements
Accelerometer Barometer GPS	Activity (e.g., step/stair counts, exercise), estimated calories burned
PPG	HR, HRR, HRV, cuff-less BP, SaO2, cardiac output, stroke volume, pulse-based rhythm detection, sleep and its stages
ECG	Single- and multi-lead ECG, continuous or as-needed monitoring, interval measurements (e.g., QTc), arrhythmia detection, electrolyte abnormalities
Oscillometer	Wrist cuff BP
Biochemical sensors	Invasive: blood glucose and electrolyte monitoring Non-invasive: sweat and saliva electrolytes and hydration status

Figure 2 Need for AI/ML to analyse large volumes of data being collected to develop clinically useful tools. Based on references.[42,43]. AI, artificial intelligence; ICD, implantable cardioverter-defibrillator; ML, machine learning; RCT, randomized controlled trials.

and just 14% would share data with tech companies (e.g. Amazon, Apple, Facebook, Google, IBM, Lyft, Intel, Microsoft, Samsung, Uber) or government organizations.[7] Consumers may believe that technology companies have the rights to view, own, or use the data for any purpose. In Europe, the General Data Protection Regulation states that everyone has the right to control and protect their own personal data.[56] Manufacturers must integrate privacy and security from conception. However, in many cases, users have to select 'opt out' settings in order to restrict the use of their information for certain purposes. Unfortunately, few people, if any, read all of the information already provided around the use of data collected by the technology they use, including Apps or social media platforms. Defining opportunities to access such data is essential for the development of academic and industry research and deserves urgent attention.

Table 1 provides an overview of some of the benefits and concerns from the individual consumer's perspective, as well as potential future directions.[6,49–51]

Perspectives of healthcare professionals

Healthcare professionals may benefit from digital health programmes through improved health outcomes (and experience or convenience of care) for patients with HF or AF. As discussed above, continuous remote monitoring of CIEDs has the potential to reduce office and hospital visits, and provide earlier detection of actionable events, device malfunction, and patients at risk. Data from wearables may provide greater insight into risk factor profiles, and medication adherence data are no longer solely dependent on patient self-reports.

Artificial intelligence algorithms are being developed to classify views from different cardiac imaging studies, and to detect or predict the presence of disease from images, ECGs, physical exams, or laboratory data.[57] For example, algorithms are being developed or in use to screen patients for the development or worsening of HF using ECG data.[47,58–60] However, many of these programmes are not yet in widespread clinical use. Using these tools for earlier detection might allow for earlier interventions, and individualization of patient management to help prevent disease progression, hospitalization, and mortality. Validation of these exciting algorithms has to be made to assess their clinical relevance.

Several studies have also reported that appointment cancellation rates were significantly reduced with the use of telemedicine (10–20%) compared with in-person appointments (~30%).[61,62] In addition, ML/AI approaches can also be used to optimize patient and procedure scheduling, predict hospital and intensive care unit needs, and staffing needs.[57] The ease of data transfer can simplify the automated analysis of ECGs, and social media can facilitate the exchange of data and knowledge between HCPs.

Table 1 Overview of advantages and potential barriers associated with digital health tools (wearables and remote monitoring)—the individual's perspective[6,49–51]

Advantages	Potential barriers
• Simplicity, at home • Greater privacy for some patients • Minimal travel • Prevention of viral infection • Combination with wearables, telemonitoring • Early detection of disease • Individual tailoring • More patient independence and self-management • Improved compliance	• Digital literacy • Health literacy • Lack of privacy for video visits for some patients • Cost of devices or internet access • Inequality in digital access • Signal quality • Lack of face-to-face (social) interaction • Impaired eyesight, diminished hearing or motor skills • Lack of non-English language tools • Data privacy • Uncertainty around what action to take in response to abnormal readings

Solutions

- Provide patient/consumer education around devices and AI, including responsive, supportive customer service platforms
- Provide instructions on when to contact a HCP, and finding and connecting with appropriate, local HCPs
- For older patients or those with impairments, tools should consider audio, visual, and motor needs—in general 'co-design' and 'co-implementation' with end users is needed from inception of digital design
- For patients where language may be an issue, programmes should integrate translation services into websites, as well as telemedicine or video technology
- Reassure patients of the privacy and security of their data
- Encourage sharing of health data. Digital health requires data, it cannot improve without patients agreeing to share some of their data (and sacrifice some privacy)
- Ensure patients have access to their own data
- Facilitate reimbursement, or provide financial assistance when needed

HCPs, healthcare professionals.

Table 2 Overview of advantages and potential barriers associated with digital health tools (wearables and remote monitoring)—the HCP's perspective[8–10,49,50,57,63–65]

Advantages	Potential barriers
• Reduce office and hospital visits • Provide earlier detection of actionable events, and device malfunction, • Screen for patients at risk • Screen patients for the development or worsening of HF • Allow for early, individualized interventions, to improve patient outcomes • Telemedicine can reduce appointment no-shows • Wearables may provide better insight into risk factors, and patient adherence to the management plan	• Digital literacy • Costs and reimbursement • Integration in EHR/work flow • Infrastructure and support • Lack of face-to-face interaction • Data privacy and legal concerns, cybersecurity • Patient trust • Navigating the plethora of programmes, and determining which have been validated and approved • Lack of transparency: Understanding findings to determine next steps • Explaining findings to patients

Solutions

- Provide regular training and education on digital technology for all personnel
- Advocate for a regularly updated, and easily searchable, online repository of validated, regulated tools and programmes
- Reassure patients of the privacy and security of their data
- Encourage patients to share their data
- Advocate for patients to have access to their own data, or are provide regular summaries
- Advocate to payers for greater reimbursement of devices, algorithms/programmes, and full service 'digital solutions' services
- Designate dedicated personnel to execute and monitor digital programmes

EHR, electronic health record; HF, heart failure.

Challenges

Many of the challenges experienced by patients are also experienced by HCPs (*Table 2*). Digital literacy and navigating through the increasing amount of data, and the number of ever-changing devices can be a problem. Despite the explosion in this area, many medical school programmes have not included digital health in their curricula. Programmes vary widely in different countries and institutions but should become standard and part of life-long learning. Moreover, new professional profiles and educational pathways such as digital nurse programmes should be developed to better serve the huge opportunities of digitalization.

The issues around privacy of patient data are compounded by concerns around ethical and regulatory aspects, and the potential for legal liability when using devices or programmes in clinical practice.[63] There are concerns about who is collecting the data, and what is being done with it. Patients may feel they are under constant surveillance, and it falls on the HCP to provide an explanation of the purpose of the monitoring and provide assurances of the privacy and security of their data.[50] Healthcare professionals may also feel that they are being monitored by their hospital, insurance companies, or other institutions.

The lack of transparency of some AI algorithms fosters a lack of confidence. It can be difficult to understand what the data mean and what information it is derived from, especially if further diagnostic tests are being considered.[63] Some algorithms are trained on too narrowly defined datasets, leading to problems with external validity

and generalizability. Accessing validation study results may also be problematic.

In the case of patient management, it is not always clear what action should be taken, for example, what threshold warrants treatment in the case of pre-diagnostic data suggesting elevated CV risk.

Choosing which tools to use, and to recommend to patients, can be a challenge for HCPs. The requirements for documentation and evidence increase with the risk profile and clinical claims of a tool. There is a balance to be made between the speed of innovation and the appropriate requirements to generate evidence for safe and effective use before putting new AI/ML products on the market. In a systematic review of 215 studies using AI/ML in CV medicine, only 10% of studies provided a clinical trial registration.[43] Often exact methods were not reported, which limits reproducibility and makes it difficult to compare findings across studies. This is often related to the fact that many programmes and devices are based on proprietary technology.[57] Thus, standards for reporting the methods and results of AI/ML research should be developed and applied.

In addition, not all smart watches/phones and other sensors may provide accurate readings. Some devices and software have been approved by the European Medicines Agency (EMA) and received CE marking. According to the EMA, software that is intended to be used for a medical purpose is a medical device, while stand-alone software for general purposes used in a healthcare setting is not.[66,67] As in the USA, many are not classified as medical devices, and are not subject to regulatory approval.[68] Many potentially useful mobile devices, websites, and other tools have no oversight or are being used for purposes outside their labelling. There is a need to bridge the gap between these direct-to-consumer devices and the medical care pathway. A further complication is that the use of regulatory-cleared (or non-cleared) devices to record measurements can be initiated by either HCPs or patients themselves. The European database on medical devices (EUDAMED), which is under development, aims to provide an up-to-date database of medical devices that are being made available in the European Union (https://ec.europa.eu/tools/eudamed/#/screen/home).

Digital tools will support HCPs, but will not 'replace' them, and while making some things easier, and arguably more accurate, constant monitoring and the need to take action when indicated, may require a lot of time and changes to the workflow, which are challenging for many clinicians and healthcare organizations. This change of workflow necessitates a redesign of diagnostic and treatment pathways not just the implementation of some digital pieces. False-positive alerts for AF can be a tremendous burden, but this has been improved by the use of improved AI algorithms to filter incoming data (*Figure 3*).[44,45] But, HCPs need the infrastructure and personnel who are trained and supported to execute and monitor digital programmes. Healthcare professional surveys report a lack of infrastructure/personnel and reimbursement as the top barriers to the use of digital health tools.[8,10] Cost will also remain an issue for many practices. There was an increase in reimbursement of remote visits and digital technologies during the COVID-19 pandemic, but this was inconsistent, and the future is uncertain.[9,10]

One of the most practical drawbacks to telehealth and remote monitoring approaches is the inability to do an adequate patient physical exam.[64,65] In a survey of US physicians, >70% felt that they were unable to properly examine patients during telehealth visits.[64] *Table 2* provides an overview of some of the benefits and concerns, as well as potential future directions.

Perspectives from developers and industry partners

The forecasted annual growth rate in the wearable technology market is >20%, and the market is expected to reach >€40 billion/year over the next 5 years with >€150 billion by 2028.[50] The COVID-19 pandemic has provided additional enthusiasm for wearable devices among both patients and HCPs. In Europe, the wearable market is

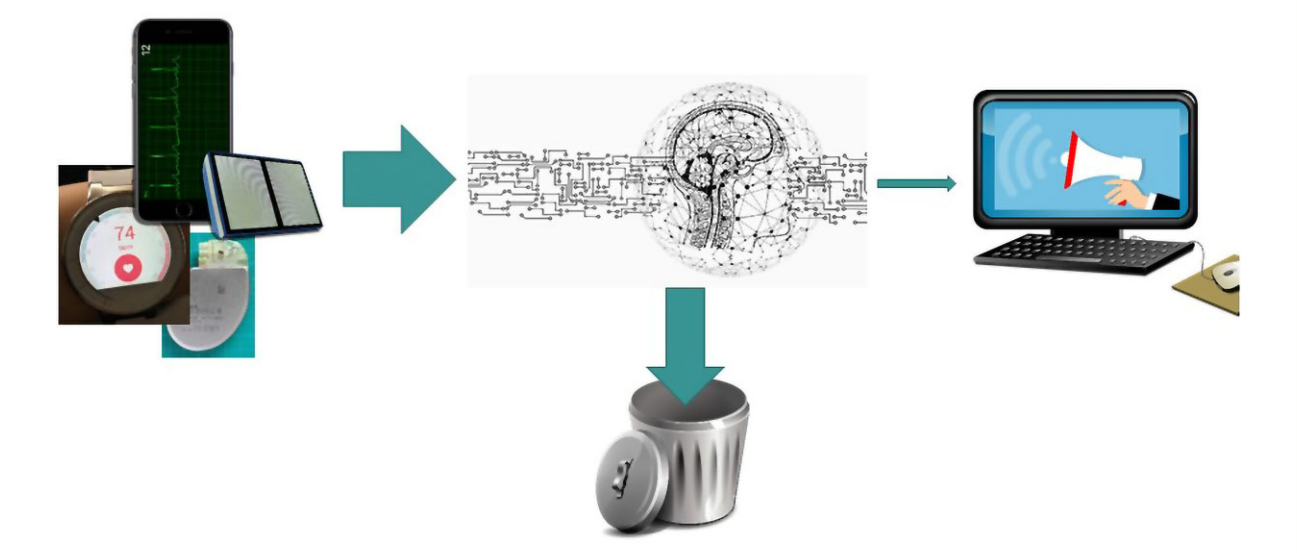


Figure 3 Using devices and AI algorithms in clinical practice to curate data[44,45]. AF, atrial fibrillation; AI, artificial intelligence.

expected to reach 170 million units by 2025 with an annual growth rate of 13%.[69] Healthcare is one of the most important areas in the wearable market.

In 2020, mobile systems generated >€125 billion in Europe, and employed almost 1.2 million people.[70] An estimated 86% of the European population subscribed to mobile services, and 78% had a smartphone. Worldwide, in 2021, there were almost 6.4 billion smartphone users, and this is increasing.[71]

Challenges

Among the greatest challenges for developers are the ever-changing technology and communication platforms (e.g. 4G vs. 5G), which require constant updates and adaptations.[5] Developers of wearable devices have to ensure accuracy of measurements (e.g. accurate heart rate readings), which in some cases can be impacted by movement and exercise.

Hardware or software specifically designed to be used for medical purposes are classified as medical devices, and require substantial effort in terms of development and testing, data security, and certification.[66,67] These solutions typically carry medical claims, are prescribed by HCP, and are therefore likely reimbursed by health insurance. However, the lines between medical-grade and consumer-grade devices are increasingly blurred.

Obtaining regulatory approval as a medical device also requires significant effort, and at substantial expense. The regulatory approval processes are highly variable across countries, in terms of what are the medical claims, what should be regulated, and the criteria for approvals. In Europe, the EMA classifies hardware or software as a medical device that requires regulatory approval, if it is intended for use in the diagnosis, prevention, monitoring, treatment, or alleviation of disease.[66] However, given the above complexities, developers may limit the medical capabilities and claims and focus their devices or health apps on wellness, fitness, or informational capabilities.[72] Thus, becoming consumer products, which may not be reimbursed. National Institute for Health and Care Excellence (NICE) has developed an evidence standard framework for the type of evidence that should be available in digital health technologies to demonstrate their effectiveness and cost-effectiveness.[73]

Compliance and ongoing patient engagement with the use of wearable technology solutions is another challenge. For example, the Apple Heart Study enrolled 419 297 participants, and an overall of 30% did not complete the end-of-study survey.[28] Even among the patients who received an irregular pulse notification ($n = 2161$), only 43% completed the study. It may be important to note that participants in these studies are self-selected and the device was not necessarily medically indicated to monitor a diagnosed medical condition as part of ongoing care. It remains unclear whether patients that use these solutions for medical indications, intervention, or medication management, will have better compliance.

Curating, managing, and integrating data, while protecting the anonymity of patients and consumers, is a sophisticated part of the design of any wearable or remote monitoring system. Patient/consumer's concerns around data privacy and mistrust of many companies can lead to difficulties obtaining the vast amount and variety of data needed to develop and validate ML/AI programmes. Overall, in a US survey only 11% of consumers were willing to share health data with tech companies, and among these respondents trust in specific tech companies varied, with 45–57% willing to share with Google, Amazon, Microsoft, and Apple, but <40% willing to share with companies like Samsung or Facebook.[7] As mentioned under the challenges for individuals, strict GDPR guidance regulates privacy issues in the EU and developers must comply with these regulations. A common mandatory specification from the governments could be an option to reassure patients

Accessing consumer/patient data is further complicated by the constant influx of new companies and new technologies. Developers enter the healthcare sector and launch consumer products to measure vital parameters, which may or may not have regulatory approval. This can create confusion and overload in the

Table 3 Overview of advantages and potential barriers associated with digital health tools (wearables and remote monitoring)—the developers' and industry partners' perspective[5,7,50,72]

Advantages	Potential barriers
• Growing, multi-billion-dollar market • Personalized medicine • Improved efficacy and safety due to constant monitoring and adaptation of therapy • Better adherence to therapy • Potential access to real-world data • Patient reported outcomes measures	• Constantly changing technology • Inconsistent regulatory requirements • Ongoing patient engagement in clinical trials and waning interest in a specific device over the long term • Demonstrating effectiveness of therapies • Accessing real-world data • Privacy concerns, patient trust • Curating, managing, and integrating data • Providing designated personnel on a large scale to monitor systems • New developers enter the healthcare sector (i.e. consumer products companies)

Solutions

- Develop technology that fills an unmet need
- Design products and algorithms to capture and analyse data from diverse populations
- Quickly and inexpensively test early potentially useful products
- Validate products in large scale, diverse populations (randomized controlled trials are preferred, pragmatic trials are useful)
- Provide cybersecurity
- Encourage development of a common/shared platform
- Encourage sharing of source code
- Encourage access to data and protocols used in published trial results
- Advocate for standardized regulatory and reimbursement processes

marketplace, leading to consumer fatigue or confusion,[7] and limiting the ability to gather real-world data on the effectiveness of interventions related to the use of digital health devices and strategies. *Table 3* provides an overview of some of the benefits and concerns from the developers' perspective, as well as potential solutions.

Implementation into healthcare systems

Developing the hardware (e.g. implantable and wearable devices) and the software (e.g. ML/AI or other algorithms) is not enough. One of the greatest roadblocks in the uptake of digital technology concerns how to use it accurately and efficiently in current clinical practice environments. Some of this concern may be unfounded. The TeleCheck-AF programme for AF management, which used remote heart rate and rhythm monitoring using a mobile phone app followed by telemedicine, was quickly implemented during the COVID-19 pandemic.[9,48] The majority of clinical centres across Europe reported no problems implementing the approach, regardless of the health care setting or the degree of prior digital health experience.

However, implementation requires expertise from industry and technology specialists, and education and support for those using the technology, both clinicians (who also need a certain degree of expertise) and patients. Many 'digital solution' companies have arisen to provide implementation services and support, including platforms that are fully integrated into electronic health record systems. They can provide ongoing innovation and updates, monitoring of incoming data from different sources, and performance metrics, and some provide additional support such as help with billing and reimbursement (e.g. Geneva Health Solutions, Philips—BioTelemetry).

Implementation programmes should focus on devices and software programmes that have regulatory approval. In addition, the system must meet minimum performance standards, be practical for use in the clinical workflow, and data should be trustworthy and explainable. Data must be collected in an open manner, and patients must be informed as to how their data are being used. For implementation to become faster and more routine in the future, it is widely recognized that there is a need for cross-platform compatibility, including integration of devices, AI algorithms, electronic health record systems, and integration of data from other sources (e.g. social and environmental data) (*Table 4*).

The generalizability of programme recommendations is highly dependent on the patient population included in data collection. The output from ML/AI algorithms can be difficult to explain, but education must be packaged in a way such that HCPs and patients understand what data have been included in the model, what filters have been applied to it, what assumptions have been made, and what the decision steps were.[63] Strong transparency would facilitate the decisions of HCPs and patients. Issues of medico-legal liability can arise as a result of errors from the use of AI programmes, or when clinicians choose not to use AI-recommended strategies or to use them when such decisions might be inappropriate.

It is clear that regulatory approval is a crucial step in the evolution of digital health into mainstream clinical practice. With rapid advances in technology, including both hardware and software, the healthcare system needs to recognize the limitations in terms of the accuracy of devices for health measurements, and software programmes for decision-making. The regulatory process ensures that data are generated and validated to optimize the efficacy and safety of digital health tools. While regulatory bodies have standards for medical devices and software, one of the challenges is the constant changes in the digital world.[68] Therefore, periodic revisions of standards are necessary. Regulatory and reimbursement processes require greater harmonization, and there is a need for a policy to address updates.

Currently, who should monitor and regulate the use of the data itself remains a challenge. Fully transparent reporting with privacy-protected, but open-access, data sharing is likely necessary to move the field forward.

Table 4 Key factors for implementation

- Use regulatory-approved devices and algorithms (updated database of approved systems. The EUDAMED database is under construction, https://ec.europa.eu/tools/eudamed/#/screen/home)
- Well documented, easily navigated, standardized process for reimbursement
- Standardized hospital policies
- Reliable data privacy
- Process for regular updates
- Common platform with systems for integration of multiple devices
- Include regular training and education on digital technology for all personnel
- Provide training for patients with devices who are enrolled in monitoring programmes
- Dedicated in house or contracted digital health personnel
- Ensure medico-legal standards are in place

Future directions and a rallying cry

Substantial progress has been made, but more work is needed. Digital technologies are already an essential part of healthcare management, and the area is constantly expanding and changing. The healthcare system needs to accelerate development of clear standards for validation and guidance for use, which are essential for practicing clinicians. *Table 5* shows some areas where medical societies such as the ESC are acting to encourage faster adoption of digital technology into cardiology. These technologies are essential for practicing clinicians and respect the interest and optimal care of patients in their individual environment.

Important questions remain that require multi-stakeholder discussions. Can we accelerate AI development by making large, diverse, and curated datasets available for product development and testing, while respecting privacy, data storage, and handling, and the 'value added' work in acquiring and curating the data? Can we create a common framework across the continuum from early adoption of new AI tools (possibly non-regulatory-approved, but cleared for investigational use) to limited adoption (regulatory-approved) to broad implementation in clinical practice (with extensive evidence for efficacy

Table 5 Steps being taken by medical societies such as the ESC

- Encourage inclusion of digital technology into medical school curricula
- Provide ongoing technology training and support, and educational updates at scientific and educational events
- Provide guidelines for use of devices and AI software programmes
- Encourage validation of all devices and AI software programmes
- Explore the feasibility of developing, and maintaining an up-to-date repository of validated devices and programmes
- Advocate for standardized, reimbursement strategies for remote monitoring solutions, devices, software, and time spent by HCP personnel
- Establish dedicated digital health committees (https://www.escardio.org/The-ESC/What-we-do/Initiatives/about-digital-health)
- Support dedicated digital health journals (e.g. EHJ-Digital Health)
- Encourage development of a legal framework to ensure data safety while allowing its use for scientific research and development purposes
- Facilitate collaboration: industry-academic-patient partnerships are needed for development and randomized validation studies to demonstrate clinical value (Digital Health Summit, October 2021)

EHJ, European Heart Journal; ESC, European Society of Cardiology.

and safety, and health technology assessment)? How best can the major stakeholders in these processes co-design and co-implement digital solutions that add value, i.e. improve outcome or experience of care and the sustainability of healthcare? Can we speed up the evaluation of new technologies so that those that add value are approved and supported through to widespread implementation more quickly, and those that do not add value are abandoned early? Finally, can we improve the individual's ability to understand and use new devices and wearables optimally without causing confusion or false concerns, to improve the efficiency of the patient–HCP relationship?

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Data availability

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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