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What is the value of digital tools for cardiovascular patients?

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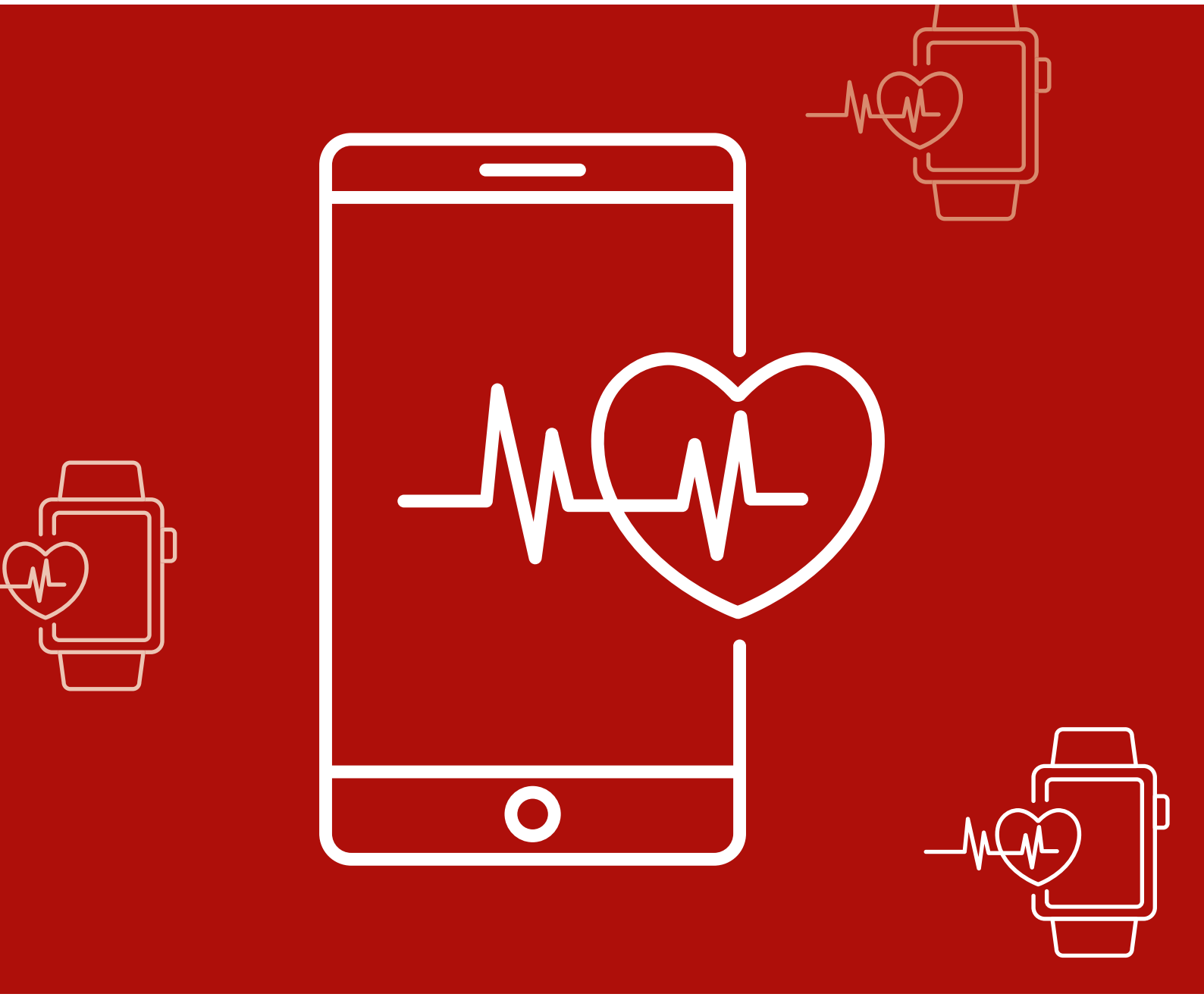

A summary of a comprehensive review of the evidence for (cost-) effectiveness for prevention and management of cardiovascular patients

Authors

Martijn Scherrenberg (1, 2) Gregory Vangenechten (1), Arne Janssen (1), Paul Dendale (1, 2)

1. Heart Centre Hasselt, Hasselt, Belgium
2. UHasselt, Faculty of Medicine and Life Sciences, Agoralaan, 3590 Diepenbeek, Belgium

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Introduction

Digital technology is rapidly evolving and is already widely used in several aspects of daily life. Digital technology has also begun to change the practice of medicine. Digital health can be defined as the use of digital technology in medicine. It encompasses a broad scope of tools to engage, motivate, monitor and empower people to prevent diseases to improve the care for patients and make healthcare systems more efficient.

This report presents the current evidence for use of digital health tools in interventions in prevention and management of cardiovascular patients. Furthermore, it looks into possible considerations regarding successful implementation of digital health.

The report summarises the findings of a detailed review of digital health research from 2000 until the end of 2019. Seven topics were intensively researched. Digital health in:

- primary prevention of cardiovascular disease (weight loss/diet counselling, physical activity, diabetes mellitus, cardiovascular risk reduction, smoking cessation and arterial hypertension);
- secondary prevention of ischaemic heart diseases;
- heart failure management;
- home-hospitalisation for heart failure patients;
- cardiac arrhythmias diagnosis and management;
- remote monitoring of cardiac implantable electronic devices; and
- big data and artificial intelligence in cardiology.

Cardiovascular disease in Europe

Cardiovascular disease includes all diseases of the heart and circulatory system. Cardiovascular disease has many forms, including ischaemic heart disease, chronic stable angina, peripheral artery disease, stroke, heart rhythm disturbances (such as atrial fibrillation), heart failure, valvular heart disease and congenital heart conditions.

The European Cardiovascular Disease Statistics, published by the European Heart Network in 2017, show that cardiovascular diseases remains the first cause of mortality and a major cause of morbidity in Europe (1). 3.9 million people in Europe and over 1.8 million people in the European Union die yearly from cardiovascular disease. This represents respectively 45% of all deaths in Europe and 36% in the European Union (1,2). *The European Cardiovascular Disease Statistics* report demonstrates a significant geographic gradient. Death rates from cardiovascular disease are significantly higher in Central and Eastern Europe (2). Over the past fifty years, a significant reduction in cardiovascular mortality has been achieved due to better prevention, diagnosis and treatment. Recent data indicate a slow-down in the reduction of mortality rates, which may be explained by a rising prevalence of obesity, diabetes and an ageing population.

Cardiovascular disease, such as heart failure, atrial fibrillation and ischaemic cardiomyopathies, takes up a large portion of the chronic disease burden, carrying an important socio-economic impact (3). The estimated cost for the European Union economy is €210 billion a year. Of that cost, around 53% is for health care costs, 26% is due to productivity losses and 21% due to informal care of people with CVD. This economic burden presents an enormous challenge to healthcare systems in Europe (4).

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What is digital health?

Digital health is most frequently defined as the use of information and communication technologies to treat patients, conduct research, educate patients and healthcare professionals, monitor acute and, mostly, chronic diseases and to monitor and compare the national public CVD status with other countries (1). Digital health is an increasingly popular research topic due to its potential to increase the well-being of millions of citizens and radically change the way health and care services are delivered to patients if designed purposefully and implemented in a cost-effective way (2).

Digital health consists of two main components, namely mHealth and telemedicine. mHealth can be further divided in the use of smartphones, tablets and wearable technologies for health services (3). Examples of mHealth interventions are smartphone applications and internet-based interventions for self-management and lifestyle monitoring. Telemedicine can be described as the delivery of remote care. It can be subdivided in two components: telerehabilitation and telemonitoring (3). In summary, the term digital health is "a broad umbrella term encompassing main components as mHealth and telemedicine as well as emerging areas, such as the use of advanced computing sciences in big data, genomics and artificial intelligence".

Digital health will most likely play a central role in healthcare innovation. Digital-based healthcare need to be better integrated, more value-based and have a stronger focus on patient outcomes and preferences.

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Digital health in primary prevention of cardiovascular disease

The burden of cardiovascular disease in Europe can be lowered through reduction of risk. Cardiovascular risk factors can be categorised as modifiable and non-modifiable. Examples of non-modifiable risk factors are age, ethnicity and gender. Both non-modifiable and modifiable cardiovascular risk factors, the latter including smoking, obesity, diabetes mellitus, high blood pressure and a sedentary lifestyle, are associated with an increased risk for cardiovascular disease. Primary prevention aims at reducing the prevalence of modifiable risk factors in a healthy population to prevent or delay cardiovascular events, i.e. heart attacks and strokes. Due to the high prevalence and the socio-economic impact of cardiovascular disease, primary prevention should be a high priority for policy makers.

Digital health can play an important role in primary prevention: internet-based tools and smartphone applications can be used for remote lifestyle monitoring, diagnosis, self-management, medication adherence, education and psychological support (1). An advantage of digital health is that it can transform prevention into a more patient-centred care by tailoring content to people's individual needs and preferences. It can also empower patients to take an active role in decisions about their health.

This report focuses on the following modifiable risk factors: high blood pressure, smoking, diabetes mellitus, overweight and obesity, and a sedentary lifestyle.

Role of digital health in arterial hypertension

Hypertension, also known as high or raised blood pressure, is a condition in which blood pressure is consistently too high and the heart has to work harder to pump blood around the body. It is a serious condition because it can lead to heart attack or stroke. It can also cause kidney failure, heart failure or other medical problems such as vascular dementia. Digital health can aid the long-term monitoring of blood pressure, in reducing therapeutic inertia, and in educating patients. Education comprises informing about the effects of behaviours, such as salt intake, alcohol and physical inactivity, on blood pressure. The term "therapeutic inertia" refers to the failure to advance therapy or to de-intensify therapy when appropriate (5).

The key points regarding digital health in arterial hypertension are the following:

- Current evidence suggests that telemonitoring could be effective in reducing blood pressure, but more research is needed to confirm the added value of telemonitoring to self-monitoring alone.
- More research is also required to confirm the cost-effectiveness of this intervention.
- Smartphone applications have much potential in remote monitoring and improving hypertensive patients' medication adherence. However, there is not yet enough evidence to confirm the effectiveness of mHealth applications in hypertension management.

Role of digital health in diabetes mellitus type 2

Type 2 diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is one of the hormones that regulate blood sugar. Long-term uncontrolled diabetes leads to serious damage to many of the body's systems, especially the nerves and blood vessels (6). Therefore, patients with type 2 diabetes are at high risk for cardiovascular disease, such as ischaemic heart disease and stroke. Glycated haemoglobin, or HbA1c, is used to monitor the average blood glucose levels of the last three months. This provides a useful longer-term gauge of blood glucose control.

The key points regarding digital health in diabetes mellitus are the following:

- Telemonitoring of blood glucose in type 2 diabetes patients seems to improve control of glycaemia, health-related quality of life and HbA1C. More trials are needed to support the implementation of telemonitoring.
- The use of text messaging and smartphone applications could also play a role in the chronic management of type 2 diabetes. Text messaging could increase therapy adherence and improve lifestyle choices. More research and larger trials will be indispensable to confirm the cost-effectiveness in comparison with standard care and telemonitoring.
- Several trials demonstrate that smartphone applications can reduce HbA1C. This suggests that smartphone applications will play a role in type 2 diabetes management in the future. More research is needed to confirm this.

Role of digital health in smoking cessation

Smoking is a major modifiable risk factor for ischaemic heart disease, as well as for certain cancers and multiple other diseases (7). Current smoking cessation interventions consist of pharmacological treatment and cognitive behaviour therapy. A barrier to successful implementation is that smoking cessation interventions rely heavily on health professionals initiating the treatment. Digital health could provide opportunities to engage less-motivated or hard-to-reach smokers.

The key points regarding digital health in smoking cessation are the following:

- Internet-based smoking cessation programmes present very contradictory results. A recent meta-analysis of 2019 suggests that internet-based smoking cessation interventions increased the odds of cessation by 29% in the short term and by 19% in the long term. However more evidence is needed to implement internet-based intervention in regular care.
- Evidence shows that text messaging is an effective intervention to improve cessation rates and that it could be a standard element of smoking cessation interventions.
- Smartphone applications could be effective; however only four trials on such interventions were published between 2015 and the end of 2019. More evidence is needed.

Role of digital health in weight loss interventions

Overweight and obesity are independent predictors for ischaemic heart disease (8). Weight loss interventions are not only important to reduce obesity, but the interventions also influence a number of major risk factors including hypertension, high cholesterol and type 2 diabetes (9). Weight loss programmes consist mainly of physical activity training and dietary advice.

The key points regarding digital health for weight loss are the following:

- Internet-based weight loss interventions have positive effects on diet choices, physical activity and weight.
- Smartphone applications can help to achieve a moderate short-term weight loss. More research is needed to demonstrate long-term results and to assess the cost-effectiveness of these interventions.
- The effectiveness of text-messaging interventions for weight loss remains debatable. Two meta-analyses demonstrated a small effect of text-messaging interventions in short-term weight loss. However, lack of long-term results indicate that further studies are required. Research is also needed on the cost-effectiveness of text-messaging interventions.

Role of digital health in increasing physical activity

Sedentary lifestyle and physical inactivity are important risk factors for ischaemic heart disease (10). Physical activity is therefore an important part of primary and secondary prevention programmes. Regular physical activity is associated with beneficial effects on insulin sensitivity, metabolic syndrome, weight, blood pressure and quality of life (11). Current guidelines recommend a minimum 150 minutes of moderate-intensity aerobic physical activity throughout the week or at least 75 minutes of vigorous-intensity aerobic physical activity (12).

The key points regarding digital health for improving physical activity are the following:

- Pedometer- or activity tracker-based interventions are associated with reduced sedentary time among adults in the short term. Larger and longer trials are still needed to evaluate long-term effects and cost-effectiveness of these interventions.
- Smartphone applications for increasing physical activity have positive effects, however the effects are small. More research and larger trials are needed to confirm the long-term maintenance of higher physical activity.
- Text messaging can lead to increased physical activity.
- The effect of online social networks, gamification and incentives has been investigated in multiple small trials. Most of these interventions show modest improvement of physical activity.

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Digital health in secondary prevention of ischaemic heart disease

Patients who have had a heart attack or revascularisation procedures are at high risk for recurrent events. Therefore, in those patients secondary prevention is important to reduce mortality, to decrease subsequent cardiac events, and to improve quality of life. In general, secondary prevention of ischaemic heart disease consists of two pillars: optimal medical therapy and a healthy lifestyle (1,2).

An important part of secondary prevention is cardiac rehabilitation. However, participation rates are disappointingly low in Europe. Barriers comprise patients' low health literacy, and transport and schedule constraints (3). Digital health has the potential to overcome these barriers and to improve cardiac rehabilitation access and uptake. The use of technology in cardiac rehabilitation is called telerehabilitation.

The key points regarding telerehabilitation are the following:

- Home-based exercise training or telerehabilitation for ischaemic heart disease patients is an effective way to deliver exercise training in patients who cannot attend centre-based cardiac rehabilitation.
- Home-based exercise training or telerehabilitation for ischaemic heart disease patients is an effective way to deliver exercise training as an add-on to centre-based cardiac rehabilitation to increase long-term effects of cardiac rehabilitation.
- Several trials suggest that telerehabilitation, whether standalone or as add-on, is cost-effective. However, larger studies in different healthcare systems, as well as more cost-effectiveness research are needed.

Digital health can also be used for long-term maintenance of a healthy lifestyle after cardiac rehabilitation. Many patients relapse into old habits after finishing cardiac rehabilitation.

Digital tools may help to maintain long-term, self-management of ischaemic heart disease after cardiac rehabilitation with an array of personal smartphone-based technologies.

The key points regarding digital health for secondary prevention of ischaemic heart disease are the following:

- Lifestyle management of ischaemic heart disease with the help of digital health tools is an effective way to optimise risk factor profiles of patients.
- Especially, telephone counselling, text messaging and smartphone applications are effective, while Internet-based interventions have failed to prove effectiveness up to now.
- Smartphone applications have the potential to provide very accessible pocket-size interventions.

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Digital health in heart failure management

Heart failure can be defined as the reduced ability of the heart to pump or fill with blood. The heart is unable to properly perform its function of pumping blood to all organs. It is a long-term condition that cannot be cured, but with treatment and lifestyle changes many people can have a good quality of life.

Heart failure is the leading cause of hospitalisation in Europe and accounts for a large part of the healthcare expenditure in Europe (2). Acute heart failure, or decompensated heart failure, is often preceded by signs and symptoms, such as weight gain, dyspnoea, reduction in physical activity etc. Remote patient management of, or telemonitoring in, patients with heart failure might help to detect early signs and symptoms of cardiac decompensation. This enables a prompt initiation of the appropriate treatment to avoid hospitalisation (3).

The key points regarding telemonitoring in heart failure patients are the following:

- Many trials have demonstrated the effectiveness of telemonitoring in reducing rehospitalisation and in improving heart failure patients' quality of life.
- Meta-analyses of these trials demonstrate significant improvement in outcomes from telemonitoring interventions, especially in the short term. However, some large multi-centre trials have failed to demonstrate effectiveness of telemonitoring.
- New randomised multicentre studies are needed to identify which telemonitoring interventions are effective.

Telemedicine, or remote monitoring, was introduced as a potential way to reduce the likelihood of deteriorating cardiac illness or the prospect of hospital readmissions (4). In addition to telemonitoring systems, which involve the transmission of information on symptoms and signs, structured telephone support is another option for long-term monitoring (4).

The key points regarding telephone follow-up in heart failure patients are the following:

- Telephone counselling can be effective in reducing hospital admission for heart failure but seems most effective in improving patients' health knowledge and self-care skills.
- Cost-effectiveness of a structured telephone counselling approach remains questionable.

Smartphone applications and text messaging are more recent tools for remote monitoring of heart failure. Text messaging gives health professionals the opportunity to interact with patients in a less intrusive way. Smartphone applications have the potential to enable pocket-size delivery of multidisciplinary heart failure care wherever and whenever the patient needs it.

The key points regarding smartphone applications and text messaging interventions for heart failure patients are the following:

- There is not yet very strong evidence for the use of smartphones in improving heart failure patients' self-management with long-term outcomes.
- Most trials have very small sample sizes and short follow-up periods.
- The potential of smartphone use in long-term management of heart failure may be considerable. But it needs to be demonstrated through long-term randomised multi-centre trials.

The heart failure guidelines of the European Society of Cardiology suggest that heart failure management must be holistic, including appropriate pharmacological and device therapy, cardiac rehabilitation, remote monitoring of cardiovascular implantable electronic devices, and regular follow-up (39). Cardiac rehabilitation is often an underestimated part of long-term heart failure management. Telerehabilitation could possibly improve the uptake of exercise training in heart failure patients.

The key points regarding telerehabilitation in heart failure patients are the following:

- There is still a debate whether telerehabilitation is effective in reducing rehospitalisation and mortality in heart failure patients.
- More research in home-based exercise training in heart failure is needed to investigate the long-term effects.

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Home-hospitalisation of heart failure

Frequent rehospitalisation of heart failure patients leads not only to increased healthcare costs; it is also associated with functional decline, confusion and in-hospital infections. So, innovative care delivery models for heart failure patients are investigated to decrease the socio-economic burden and negative impact on quality of life (1-5).

Hospital at home, or home-hospitalisation, is the delivery of acute hospital-level care in a home setting. Hospital at home comprises only the treatment of an acute heart failure decompensation at home which normally takes place in the hospital and has to be distinguished from permanent follow-up, telemonitoring, telerehabilitation and early discharge interventions. During the home-hospitalisation intervention, a physician or healthcare professional delivers daily home care during the acute decompensation of heart failure. The daily home care can consist of diagnostic tests, including clinical examination, electrocardiograms, blood samples, and administering heart failure therapy, such as intravenous fluids or medications (6).

The key points regarding home-hospitalisation in heart failure patients are the following:

- Home-hospitalisation supported by IT technology could potentially reduce the need for hospital beds and improve heart failure patients' outcomes and quality of life.
- Home-hospitalisation research is still in its infancy, awaiting strong proof from randomised controlled trials.
- The necessary technology and organisation can, nevertheless, already be used to help in safely discharging heart failure patients earlier.

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Digital health in cardiac arrhythmia diagnosis and management

Cardiac arrhythmias are defined as irregular, very fast or very slow heart rates. Tachycardia is the presence of a fast heart rate (above 100 beats per minute). Bradycardia is very slow heart rate (below 60 beats per minute). Common symptoms of cardiac arrhythmias are palpitations (sensations of a uncomfortable, irregular heartbeat), chest pain, dizziness, dyspnoea and syncope. The most prevalent arrhythmia, especially in elderly people, is atrial fibrillation.

Diagnosis of cardiac arrhythmias is difficult because cardiac arrhythmias are often intermittent. Ambulatory electrocardiogram (ECG) monitoring is therefore used to monitor ECG data over an extended period of time. This permits evaluation of dynamic and transient differences of the heart rhythm. However, ambulatory Holter monitoring test, a continuous test to record a person's heart rate and rhythm for 24 hours, is still limited in duration and

can therefore still miss a significant portion of cardiac arrhythmias. The use of smartphone or smartwatch applications and handheld devices could help in long-term monitoring of intermittent cardiac arrhythmias. They allow patients to measure their heart rhythm at the moment they experience symptoms.

The key points regarding smartphone interventions for arrhythmia detection patients are the following:

- Smartwatches, handheld devices and bio patches show some promising results for long-term monitoring and mass screening; however more research is needed to confirm their accuracy and cost-effectiveness.
- More research is also needed to investigate the role and implementation of digital health monitoring in current workflows and care pathways.

Prehospital ECG comprises the use of telemedicine to transmit an ECG to the physician before the patient arrives in the hospital. This can be used in patients with symptoms suggestive of heart attack. The ECG can be taken at the home of the patient or in the ambulance. E-transmission of the ECG accelerates the diagnosis of ischaemic heart disease. This can optimise the referral to the right centre (centres that are able to perform percutaneous coronary intervention) and speed up the start of treatment.

The key points regarding prehospital emergency ECG are the following:

- Prehospital ECGs can be transmitted through telemedicine devices, telephone, smartphones etc.
- Multiple studies demonstrated that prehospital ECG is associated with lower door-to-balloon time and increased survival.

Atrial fibrillation is an arrhythmia characterised by rapid and irregular beating of the atrial chambers of the heart. This can cause pooling of blood leading to the formation of blood clots. These blood clots can migrate to the brain and occlude a brain artery causing a stroke. Therefore, adherence to oral anticoagulation therapy is important in preventing strokes and systemic thromboembolism in atrial fibrillation (1,2). Non-adherence or failed persistence can result in poor clinical outcomes and increased healthcare costs (3).

The key points regarding digital health for anticoagulation treatment in atrial fibrillation are the following:

- Digital health technology can increase patients' adherence to treatment.
- No good cost-effectiveness studies are available, but it may be expected that these low-cost interventions will prove to be cost-saving.

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Digital health for cardiovascular implantable devices

The term cardiac implantable electronic device (CIED) comprises pacemakers, implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy (CRT). A pacemaker device could be used to generate electrical impulses to regulate the electrical conduction system of the heart in patients with a particular type of heart block, a delay in the electrical signals travelling through the heart, that make the heart to beat too slowly and patients whose heart is beating too fast. The goal of an ICD is to prevent sudden cardiac death in patients at high risk for life-threatening cardiac arrythmias. ICDs keep track of the heart rate and when an abnormal heart rhythm is detected the device will deliver an electric shock to restore a normal heart rhythm. A CRT is the insertion of two electrodes in respectively the left and right ventricle of the heart to treat heart failure by coordinating the function of left and right ventricle. A CRT device is indicated when patients suffer from a low ejection fraction or when the electrical activity of the heart has been compromised.

Currently, CIEDs contain multiple sensors and technologies enabling daily monitoring of several important parameters in heart failure and cardiac arrhythmias (1). Most current cardiac resynchronisation therapy and defibrillator devices can monitor daily physical activity, arrhythmias and thoracic impedance, which help the early detection of heart failure decompensation. Furthermore, pacemakers and internal loop recorders permit long-term monitoring of cardiac rhythm and can help to detect paroxysmal (intermittent) atrial fibrillation or severe ventricular arrhythmias.

The key points regarding remote monitoring of CIEDs are the following:

- Most trials and meta-analyses demonstrate that remote monitoring of CIEDs is effective in reducing rehospitalisation, mortality and healthcare costs.
- The use of intrathoracic impedance monitoring with CIEDs, an early warning of impending decompensation in heart failure patients, needs further investigation.

The key points regarding patients and health professional satisfaction and acceptance of remote monitoring of CIEDs are the following:

- Patient-reported health status and ICD acceptance did not differ between patients on remote monitoring and patients receiving usual care.
- Studies demonstrate high satisfaction with remote monitoring.
- Patients with a preference for remote monitoring were more likely to be higher educated and in employment.

The intracardiac pressures, such as the pressure in a pulmonary artery, are important predictors for impending pulmonary congestion and could help to predict heart failure decompensations in time to adapt treatment and prevent hospital admissions (2).

The key points regarding use of wireless implantable hemodynamic monitoring systems are the following:

- The CHAMPION trial demonstrates a large reduction in hospitalisation after six months follow-up for patients with severe heart failure.
- More research is needed to consistently implement implantable hemodynamic monitors in standard care, but most trials show promising results.

Remote monitoring of CIEDs may help in early detection of cardiac arrhythmias and, thus, reduce heart failure decompensation, risk of stroke and sudden cardiac death. Multiple studies demonstrate that cardiac arrhythmias diagnosed during remote monitoring of CIED have a significant influence on major health outcomes. Remote monitoring could also be used to adapt anticoagulation therapy in paroxysmal atrial fibrillation patients.

The key points regarding remote monitoring of CIEDs for detection of cardiac arrhythmias are the following:

- Arrhythmias detected by remote monitoring are predictive of adverse events.
- Device-detected atrial fibrillation is associated with an increased risk of ischaemic stroke.
- Changing the oral anticoagulation administration based on arrythmia detection by CIED is feasible.

Implantable loop recorders (ILR) have become increasingly popular for long-term monitoring of cardiac rhythm. ILRs are small devices that continuously monitor the heart rhythm of patients. Multiple studies demonstrated that ILR can have an important role in the diagnosis of unexplained syncope (3-7). ILR can also help in the diagnosis of paroxysmal atrial fibrillation; it is well established that Holter monitoring test (electrocardiogram) frequently misses paroxysmal atrial fibrillation. ILR provides the opportunity for long-term rhythm monitoring (8).

The key points regarding implantable loop recorders are the following:

- Implantable loop recorders are effective in the diagnosis of unexplained syncope.
- Implantable loop recorders can play an important role in the diagnosis of paroxysmal atrial fibrillation and life-threatening arrhythmias.

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Big Data and artificial intelligence in cardiology

Big Data can be defined as large datasets that cannot be analysed, searched, interpreted, or stored using traditional data-processing methods (1). These datasets are mostly processed and analysed with the application of artificial intelligence and machine learning algorithms (2). The most used definition of Big Data was introduced by Doug Laney in 2001 and was known as the 3Vs: volume, variety and velocity (2,3). Currently, Big Data is defined as the 4Vs after the addition of 'veracity 'or even 5Vs when you add 'variability'. Big Data sources could be electronic medical records in clinical practice, but also data from wearable devices, biosensors, genome sequencing, patient-reported outcomes, data about internet use and much more (4).

The prominence of Big Data goes hand in hand with the rise of artificial intelligence (5). Artificial intelligence is defined by the European Commission as: "Systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals. Artificial intelligence-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems) or artificial intelligence can be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications) (5,6)."

Therefore, artificial intelligence and machine learning may help to process and analyse big data sets and present them as smaller lumps of understandable information enabling doctors to provide more efficient, more convenient, more personalised, and more effective care (7). The evidence for the use of Big Data analytics is increasing. Big Data analytics can be used for predictive risk models, pharmacogenomics, ECG diagnosis, image analysis and can facilitate research.

However, ethical considerations of artificial intelligence need attention and demand a balanced regulatory approach weighing digital innovations against protection of personal data.

The potential applications of artificial intelligence in cardiology are the following (5):

- Big Data analysis can identify trends or interpret the gigantic amount of genetic information that would predispose someone to a particular disease.
- Big Data and artificial intelligence could link relevant data collected by different types of service providers (e.g. social welfare, health and emergency care) to gain a better insight into the patterns of healthcare use by disadvantaged groups and make service improvements to potentially reduce health inequalities.
- The development of new medicines with real added value can be fostered and potentially accelerated.
- Big Data analysis with artificial intelligence could detect new associations from the current available databases and these newly identified causal relationships could lead to the development of new therapies or quicker diagnosis.
- The patient selection for clinical trials could be based on DNA profiling, which provides biomarkers for targeted treatment. This can lead to more personalised and precise drug development and reduce the cost of drug research.
- Artificial intelligence can help in triaging patients to the right care. Artificial intelligence can, based on the patient's medical history and current symptoms, decide the need to see a doctor. An example of this is the Babylon application (8).
- Big Data analysis could be used to do population health analytics, which provide the possibility of optimising certain healthcare pathways of specific diseases.
- Big Data analytics can be used for new predictive risk models based on all information collected. This can also result in the identification of new risk factors.
- Artificial intelligence can improve the accuracy of radiologist and cardiologist in the interpretation of scans such as CTs, echocardiography or MRIs.

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Considerations for implementation of digital health

The detailed review, which this report summarises, demonstrates the potential for digital health interventions to improve health outcomes and potentially save costs for cardiovascular prevention, detection and management (1). Still, only few digital health tools are already implemented in standard care.

Patient-related considerations for implementation could be access to the Internet and to digital tools, privacy and data security concerns, lack of personal motivation and low digital literacy (1,2). Furthermore, it is important to consider the potential aggravating impact of digital health on inequalities in health. Low health or digital literacy, lack of user-friendliness and doubts over the meaningfulness of information can create new health inequalities (3).

Recommendations for reducing patient-related considerations could be:

1. Increasing access to digital health technology and to reduce pressure to buy the newest digital tools
   a. Governments could invest in an infrastructure where all citizens have access to affordable digital health.
   b. Governments could create frameworks to make all digital health tools accessible for everyone, even to people with outdated technology.

2. Improve digital literacy with education
   a. There is a growing need to educate and train individuals in health and digital literacy, especially the vulnerable and at-risk groups.

Next to patient-related consideration, there are also considerations regarding health professionals, and legal and ethical issues:

1. Digital health implementation in the current workflow

Digital health could potentially reduce the workload of healthcare professionals by taking over some of the daily tasks. In reality though, digital health is often added to existing care rather than being streamlined into it leading to an increased workload (1). This results in the perception that digital health implementation always results in higher workloads. Therefore, it is important to pay attention to the integration in the clinical workflow during the development of digital health tools.

2. Not enough strong evidence for digital health interventions

More research and especially bigger randomised controlled trials are needed to demonstrate the effectiveness of digital health interventions. Once there is unequivocal proof that such interventions are effective, this should persuade physicians to use them. Improved patient health outcomes are also important to persuade governments and healthcare organisations to invest in these digital health strategies (1).

3. Training of health professionals

Another important consideration is that current healthcare professionals are not trained to use digital health in the care of patients. Therefore, current and future health care professionals must be educated about the opportunities and the use of digital health.

4. Reimbursement of digital health

In most EU countries, there is no reimbursement of digital health and health professionals are not paid for digital health services (1). Health professionals can be hesitant to use innovative digital health because they are not compensated for these efforts.

5. Lack of a uniform legal and ethical framework

Lastly, at this moment a clear regulatory framework for the use of digital health and artificial intelligence in healthcare is lacking (1). This results in uncertainties such as who is responsible for decisions made by artificial intelligence systems or who is responsible for data leakage when a remote monitoring system is hacked.

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Conclusions

The burden of cardiovascular disease in the European Union and Europe is high. Each year cardiovascular disease causes over 1.8 million deaths in the European Union (36% of all deaths) and millions of people live with cardiovascular disease. This results in a significant challenge for healthcare budgets and systems. For this reason, innovative ways to address these challenges, such as digital health, are explored to deliver better care to patients at a reasonable cost.

In primary prevention, evidence suggest that digital health can play an important role in lifestyle management interventions to reduce cardiovascular risk. In secondary prevention multiple trials suggest that telerehabilitation can be as effective as centre-based cardiac rehabilitation. Lifestyle management programmes delivered with digital health could be effective to prevent recurrent heart attacks.

The role of digital health in heart failure management remains under discussion especially in telemonitoring. Also, more research is needed to prove the effectiveness of telerehabilitation in a heart failure population. Digital health for atrial fibrillation detection is a relatively new field. There is still a need for more multi-centre randomised controlled trials, but current evidence suggests that it can be a valuable tool for atrial fibrillation detection and mass screening. Remote monitoring through CIEDs is effective in reducing rehospitalisation, mortality and healthcare costs.

Digital health gives patients and health professionals the chance to transform current healthcare models. However, there is still a need for big multi-centre trials to confirm the effectiveness and the cost-effectiveness of these digital interventions in cardiology. Lastly, digital health has great potential, but it is important not to forget patients with lower digital literacy. Attention to the needs of elderly, disabled and cultural differences between ethnic groups is needed.

Overall, digital health research is trending, however most trials have only small sample size, have slightly different interventions, have only short term follow-up or use different endpoints. This makes it very difficult to make general conclusions about digital health in cardiology. Therefore, there is a need for more investments in long-term multicentre trials to reveal the effectiveness but also the cost-effectiveness of digital health.

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