

ESC e-Cardiology Working Group Position Paper: Overcoming challenges in digital health implementation in cardiovascular medicine

European Journal of Preventive
Cardiology
0(00) 1–12
© The European Society of
Cardiology 2019
Article reuse guidelines:
sagepub.com/journals-permissions
DOI: 10.1177/2047487319832394
journals.sagepub.com/home/ejpc



Ines Frederix^{1,2,3,4}, Enrico G Caiani^{5,6}, Paul Dendale^{1,3},
Stefan Anker⁷, Jeroen Bax⁸, Alan Böhm^{9,10}, Martin Cowie¹¹,
John Crawford¹², Natasja de Groot¹³, Polychronis Dilaveris¹⁴,
Tina Hansen¹⁵, Friedrich Koehler¹⁶, Goran Krstajić¹⁷,
Ekaterini Lambrinou¹⁸, Patrizio Lancellotti^{19,20}, Pascal Meier²¹,
Lis Neubeck²², Gianfranco Parati²³, Ewa Piotrowicz²⁴,
Marco Tubaro²⁵ and Enno van der Velde⁸

Abstract

Cardiovascular disease is one of the main causes of morbidity and mortality worldwide. Despite the availability of highly effective treatments, the contemporary burden of disease remains huge. Digital health interventions hold promise to improve further the quality and experience of cardiovascular care. This position paper provides a brief overview of currently existing digital health applications in different cardiovascular disease settings. It provides the reader with the most relevant challenges for their large-scale deployment in Europe. The potential role of different stakeholders and related challenges are identified, and the key points suggestions on how to proceed are given. This position paper was developed by the European Society of Cardiology (ESC) e-Cardiology working group, in close collaboration with the ESC Digital Health Committee, the European Association of Preventive Cardiology, the European Heart Rhythm Association, the Heart Failure Association, the European Association of Cardiovascular Imaging, the Acute Cardiovascular Care Association, the European Association of Percutaneous Cardiovascular Interventions, the Association of Cardiovascular

¹Department of Cardiology, Jessa Hospital, Belgium

²Antwerp University Hospital (UZA), Belgium

³Faculty of Medicine and Life Sciences, Hasselt University, Belgium

⁴Faculty of Medicine and Health Sciences, Antwerp University, Belgium

⁵Department of Electronics, Information, and Bioengineering, Politecnico di Milano, Italy

⁶Institute of Electronics and Information and Telecommunication Engineering, Consiglio Nazionale delle Ricerche, Italy

⁷Division of Cardiology and Metabolism, Berlin-Brandenburg Center for Regenerative Therapies (BCRT), partner site Berlin, Charité Universitätsmedizin Berlin, Germany

⁸Department of Cardiology, Leiden University Medical Centre (LUMC), The Netherlands

⁹Department of Acute Cardiology, The National Institute of Cardiovascular Diseases, Slovakia

¹⁰Faculty of Medicine, Slovak Medical University, Slovakia

¹¹National Heart and Lung Institute, Imperial College London, UK

¹²International Advisory Group, Healthcare Information and Management Systems Society (HIMSS), UK

¹³Department of Cardiology, Erasmus Medical Center, The Netherlands

¹⁴Department of Cardiology, Hippokraton Hospital, Greece

¹⁵Department of Cardiology, Zealand University Hospital, Denmark

¹⁶Centre for Cardiovascular Telemedicine, Charité – Universitätsmedizin, Germany

¹⁷Faculty of Medicine, University of Osijek, Croatia

¹⁸Department of Nursing, Cyprus University of Technology, Cyprus

¹⁹University of Liège Hospital, GIGA CardioVascular Sciences, Belgium

²⁰Gruppo Villa Maria Care and Research, Anthea Hospital, Italy

²¹Department of Cardiology, University Hospital Geneva HUG, Switzerland

²²School of Health and Social Care, Edinburgh Napier University, UK

²³IRCCS Istituto Auxologico Italiano, University of Milano-Bicocca, Italy

²⁴Telecardiology Center, Institute of Cardiology, Poland

²⁵ICCU – Cardiology Division, San Filippo Neri Hospital, Italy

Developed in collaboration with the European Society of Cardiology (ESC) Digital Health Committee, the European Association of Preventive Cardiology (EAPC), the European Heart Rhythm Association (EHRA), the Heart Failure Association (HFA), the European Association of Cardiovascular Imaging (EACVI), the Acute Cardiovascular Care Association (ACCA), the European Association of Percutaneous Cardiovascular Interventions (EAPCI), the Association of Cardiovascular Nursing and Allied Professions (ACNAP) and the Council on Hypertension (CHT).

Corresponding author:

Enrico Caiani, Politecnico di Milano, DEIB, Via Ponzio 34/5, 20133 Milano, Italy.

Email: enrico.caiani@polimi.it

Nursing and Allied Professions and the Council on Hypertension. It relates to the ESC's action plan and mission to play a pro-active role in all aspects of the e-health agenda in support of cardiovascular health in Europe and aims to be used as guiding document for cardiologists and other relevant stakeholders in the field of digital health.

Keywords

Digital health, cardiovascular disease, digital cardiology, challenges, position statement

Received 27 November 2018; accepted 30 January 2019

Introduction

Results from the European Society of Cardiology (ESC) Atlas project (a compendium of cardiovascular disease statistics compiled by the European Heart Agency) indicated that there were ≈ 83.5 million people living with cardiovascular diseases in the European member countries in 2015.¹ Globally, deaths due to cardiovascular disease increased by 41% as the world population grows and ages. The World Health Organization (WHO) global action plan (2013–2020) for the prevention and control of non-communicable diseases furthermore describes cardiometabolic risk management to be a high priority focus area.² Despite the availability of effective guideline-based treatment options, long-term benefits of these treatments are often disappointing due to low uptake and/or non-adherence.^{3,4} As an example, the ESC guidelines recommend secondary prevention programmes, i.e. cardiac rehabilitation (CR), for ischaemic heart disease to prevent recurrent disease and improve prognosis.^{5–7} A recent systematic review pooled data on the participation and adherence to CR programmes (29 included studies, both prospective/retrospective cohort studies and cross-sectional studies, $N > 350,000$ patients). The review indicated that there is still room for improvement.⁸ Both patient, healthcare provider and health system-based barriers are responsible for this.⁹ Digital health-based care delivery provides the opportunity to redesign and improve care after diagnosis and discharge thanks to innovations in telecommunication technologies (i.e. cardiac telerehabilitation).¹⁰ This novel care delivery strategy has been identified by the European Association of Preventive Cardiology (EAPC) in collaboration with the Acute Cardiovascular Care Association (ACCA) and the Association of Cardiovascular Nursing and Allied Professions (ACNAP) as a promising way to tackle the challenges inherent in conventional cardiac treatments.¹¹ Similar to secondary prevention, the application of digital health could be of value in other cardiovascular disease settings. In addition, digital health could play a very significant role in primary prevention, in which solutions such as mobile applications,

text messaging and monitoring sensors for self-tracking, as well as online behavioural counselling, have the potential to improve lifestyle through positive behaviour change theory, in particular against poor diet, smoking, and lack of physical activity.¹²

The objectives of this position paper are to: (a) provide the reader with a succinct overview of the main digital health applications in different cardiovascular disease settings; (b) highlight the most important challenges/barriers for large-scale digital health deployment in cardiology; and (c) provide the reader with a plan on how to address these challenges/barriers. This position paper relates to the ESC's action plan to play a pro-active role in all aspects of the e-health agenda in the support of cardiovascular health in Europe and beyond.¹³ It has the ambition to contribute to the actions as defined in the ESC e-health roadmap by highlighting the role of digital health strategies in cardiovascular disease and by providing recommendations on how to overcome contemporary barriers related to large-scale digital health deployment. The active involvement of the ESC Digital Health Committee¹⁴ in the finalisation of this statement adds relevance to its content and ascertains that it reflects the ESC's vision.

Definition and main applications of digital health in different cardiovascular disease scenarios

In this position paper, digital health is referred to the use of information and communication technologies to treat patients and convey healthy lifestyles (primary prevention), conduct research, educate healthcare professionals, track diseases and monitor public health as an update of the previous definition of e-health ('the use of emerging information and communication technology to improve or enable health and healthcare delivery').¹⁵

Digital health is used as a general term, encompassing e-learning, remote monitoring (i.e. telemonitoring), structured telephone support, telerehabilitation, teleconsultation and m-health apps. e-Learning is defined as the provision of medically and scientifically founded pathology-specific information to patients, using

interactive and web-based educational material.¹⁶ Telemonitoring involves the transfer of physiological data through transmission technologies such as telephone lines, broadband, satellite or wireless networks.¹⁶ Structured telephone support means monitoring and/or self-care management delivered using classic telephone technology.¹⁷ Telerehabilitation means rehabilitation from a distance by using one or several devices monitoring and communicating patient-specific information to the caregivers. It includes both telecoaching (i.e. coaching from a distance by email/SMS/telephone), social interaction, telemonitoring, e-learning and focuses on all cardiac rehabilitation core components.¹⁰ Teleconsultation involves consultation by remote telecommunications, generally for the purpose of diagnosis or treatment of a patient at a site remote from the primary physician, and may include generalist–specialist, specialist–specialist, patient–specialist, or patient–generalist–specialist relationship. m-Health apps or mobile applications are stand-alone software that operate on a smartphone, tablet, or other mobile device intended to be used as service provision tool for cardiac patients.¹⁸ A larger deployment and utilisation of these digital health services is expected in the near future due to several factors:

- Increased life expectancy, which results in a larger cohort of chronic patients of older age, with associated reduced or impeded mobility;
- Shortage of physicians and nurses to cover the future health needs of an ageing population, despite an increase in health workers in the past decade;
- Larger territory covered by wireless network communication, allowing accessibility to digital health resources and convenience for their utilisation, in particular for remote and underpopulated areas.

Table 1 summarises the main digital health solutions in the setting of primary and secondary prevention of ischaemic heart disease, in chronic heart failure and atrial fibrillation. Evidence is accumulating, especially in the field of chronic heart failure. There remains, however, a need for robust clinical research focusing on hard outcomes with long-term follow-up and including economic analyses in order to demonstrate the clinical impact and value for money of these digital health approaches.

Challenges/barriers for large-scale digital health deployment in cardiology

Patient-related barriers for digital health deployment

Developments in digital health are still, to a large extent, technically driven rather than based on needs

and expectations of patients (i.e. there is a lack of co-creation with patient involvement in design) with implications for the complexity and widespread use of digital health services.²⁶ Patient-related barriers hindering large-scale deployment of these services include user characteristics and health status, issues around privacy, security and quality concerns, lack of personal motivation, and accessibility to digital resources.^{40–47} Well-known user characteristics associated with lower digital health usage include older age, low health literacy and low socioeconomic and health status. Previous research on sociodemographic predictors of e-health use among adult internet users ($N=2358$) showed that patients with lower levels of education had significantly lower odds of going online to look for a healthcare provider, using email or the internet to communicate with a doctor, tracking their personal health information online, using a website to help track diet, weight, and physical activity, or downloading health information to a mobile device.⁴⁸ Also, according to a German cross-sectional study ($N=2000$), 54.3% of the included participants were found to have limited health literacy.⁴⁹ The strong link between health literacy and socioeconomic status has been confirmed by the results of the European Health Literacy survey (1000 people for each of the eight participating countries), where financial deprivation was found to be the strongest predictor of low health literacy.⁵⁰

In particular, low socioeconomic status may even be the most important and persistent barrier for digital health adoption. Despite the potential of digital healthcare in supporting older patients with complex health and social needs,⁵¹ studies comparing digital health uptake in such patients according to their socioeconomic status are currently lacking. A recent systematic review proposes to differentiate between the social inequalities perspective affecting the access from those affecting the use of these technologies, as factors and mechanisms may differ, and variations in use importantly shape social inequalities in health, thus suggesting to investigate emerging technologies in lifestyle health, genomics and the increased use of personalised devices in health, in which previous literature is currently lacking.⁵²

Lack of personal motivation can be due to low perceived value in the offered digital health service, or a lack of understanding of the changing roles of patient and healthcare provider. Worries about receiving a poorer level of care due to the impersonal nature of digital services are also reported. Lack of support from family members, friends or peers has implications for not signing up to digital services, whereas lack of clinical endorsement has been described as a barrier if patients feel that their physicians do not promote or want to use these services themselves. Preferences may

Table 1. Non-exhaustive list of digital health applications in different cardiovascular disease settings.

Author(s)	Digital health application	Classification	Explanation
<i>Primary prevention of cardiovascular disease</i>			
Parati G, et al.; Omboni S, et al.	Home BP monitoring (TeleBPCare study)	Non-invasive telemonitoring	Home BP monitoring fights physicians' inertia and patients' poor adherence to treatment. ^{19–22}
Milani RV, et al.	Home BP monitoring	Non-invasive telemonitoring	Home BP monitoring more effective in improving hypertension control than usual care. ²³
Parati G, et al.	ESH CARE app	m-Health apps	App proposed by Italian and European Society of Hypertension. Reliable tool for patient-doctor interactions and remote monitoring of hypertensive patients. ²⁴
<i>Secondary prevention of ischemic heart disease</i>			
Wolf A, et al.	e-Health diary and symptom tracking	Non-invasive telemonitoring	Telemonitoring increases patients' adherence to healthy lifestyle behaviors, and allows them to take a more pro-active role with more self-control and health consciousness. ²⁵
Saner H, et al.; Frederix I, et al.; Kraal JJ, et al.	Telerehabilitation (Telerehab II, Telerehab III, Fit@Home study)	Telerehabilitation	Telerehabilitation non-inferior to center-based CR as regards to physical fitness, physical activities and QoL. Telerehabilitation cost-efficient innovative care strategy (Fit@Home, Telerehab). ^{26–29}
<i>Chronic heart failure</i>			
Inglis SC, et al.	Non-invasive telemonitoring and structured telephone support	Non-invasive telemonitoring and structured telephone support	Recent meta-analysis on non-invasive telemonitoring and/or structured telephone support in HF versus usual care, showed the former to reduce all-cause mortality and HF-related hospitalisations. ³⁰ Individual Tele-RCT's in HF however, show a huge variety of results.
Landolina M, et al.; Böhm M, et al.; Hindricks G, et al.; Morgan JM, et al.	Implant-based telemonitoring (EVOLVO, OptiLink HF, IN-TIME, REM-HF, and MORE-CARE study)	Invasive telemonitoring	Invasive telemonitoring can theoretically assure early detection of worsening HF and indicate the necessity for pre-emptive interventions. The currently available evidence however, is inconclusive with regard to its clinical benefits. ^{31–34}
ESC Education; Educator for Heart.org	Remote education on HFA, ESC and AHA websites	e-Learning	Scientific evidence is lacking, but e-Learning is hypothesised to improve HF patients' disease-specific knowledge and hence their active involvement in their own chronic management. ^{35,36}
Piotrowicz E, et al.	Home-based rehabilitation	Telerehabilitation	Digital health application that has been shown to be well accepted, safe, effective, with high adherence rates among HF patients. ³⁷
<i>Atrial fibrillation</i>			
Halcx JJP, et al.	AliveCor Heart Monitor	Non-invasive telemonitoring	Several diagnostic methods of arrhythmia detection utilising mobile monitoring devices connected with smartphones have been utilised. There is an abundance of new companies working on sensor technologies,

(continued)

Table 1. Continued.

Author(s)	Digital health application	Classification	Explanation
Kotecha D, et al.	My AF app & AF Manager app	m-Health apps	remote care and personalised management. ³⁸ Designed by the ESC to enhance patient education, improve communication between patients and healthcare professionals, and encourage active patient involvement in the management of their condition. ³⁹

BP: blood pressure; ESH: European Society of Hypertension; CR: cardiac rehabilitation; QoL: quality of life; HF: heart failure; RCT: randomised controlled trial; HFA: Heart Failure Association; ESC: European Society of Cardiology; AHA: American Heart Association; AF: atrial fibrillation.

also impact digital health deployment: studies have shown that more citizens are favourable to using digital health solutions as a complement to in-person doctor visits rather than as a substitute. In addition, the type of digital technology provided, such as internet-based or mobile application-based services, may play a pivotal role with regard to the uptake in a particular population.

Physician-related barriers for digital health deployment

Wireless technologies and digital health solutions offer considerable promise because they allow for easier daily patient monitoring and feedback than approaches involving clinical personnel. Contrasting this scenario is the perception of contemporary healthcare professionals that heavy time investments are needed to review incoming data and provide feedback to the patients. One of the causes of this perception is that digital healthcare is mostly added 'on top of' existing care rather than being blended in current care delivery. As an example, nurse-led telemonitoring programmes for heart failure patients are set up without reducing/adapting the timing and frequency of conventional hospital-based appointments by the treating cardiologists at the hospital, thus increasing both the costs and time investments.

Lack of infrastructure, clarity in regulation and standardisation, incentives, knowledge and training among professionals in digital health tools are the other main barriers for physicians not to use this novel care delivery strategy.⁵³

Legal and ethical issues

Additional concerns regarding privacy, security, and data confidentiality could limit the pervasiveness and uptake of digital health solutions in Europe. In particular, the number of mobile applications related to health

(m-health apps) is growing rapidly, but only a limited number have been tested for efficacy and quality. In this field, a lot of new business activity has been developed, in particular through the creation of start-ups, where primary prevention goals and entrepreneurial activities are sometimes difficult to be distinguished. In this rapidly evolving scenario, it is a common understanding that there are health and safety risks related to m-health apps that need to be handled with regard to their clinical evidence, claims on purpose and functions, testing and validation of their performance. The broad categorisation utilised for m-health apps in common app stores (medical, lifestyle) potentially create confusion in the consumer to understand the intended use of the app, as well as it might limit the physicians' confidence in these tools in view of possible professional liability.⁵⁴ To tackle the lack of specific legislation focusing on m-health apps, in the past few years specific documents have been deployed by national authorities (such as the National Institute for Health and Care Excellence (NICE) in the UK, or the French Medicines Regulatory Agency (ANSM) in France), as well as regional certification programmes (Agencia de Calidad Sanitaria de Andalucia, Fundació TIC Salut Social de Catalunya) have been developed.

Also the EU bodies competent in medical device regulation, as well as the US Food and Drug Administration in the USA, are acting by applying higher scrutiny on possible malpractice, by stimulating an industry-based code of conduct, and by extending legislation for 'software as medical devices' to apps. However, the need for higher regulation in this field is modulated with the will to stimulate entrepreneurial activities in the digital market.

Interoperability and technical considerations

Contemporary digital healthcare delivery programmes are characterised by a multitude of interoperability and technical constraints, rendering short-term large-scale

deployment challenging. Telemonitoring involves the transfer of measured physiological data (e.g. ECG, blood pressure (BP), etc.), from peripheral sensors (wearable or implantable devices such as implantable cardioverter defibrillators and/or atrial fibrillation detection devices) to a centralised platform, encompassing the use of wireless communication networks, processing units, software, and algorithms for data capture, processing and decision support. This process involves many challenges, such as technological capabilities and system efficiency, reliability and trustworthiness, interoperability, data integrity and quality, often accompanied by the absence of a robust validation of the results and lack of generalizability.^{55,56} Concerns related to the liability for doctors in the (lack of) review of data transmitted outside office hours are also raised. Related to interoperability, the accessibility of the acquired data for visualisation and analysis, as well as for possible integration into the patient electronic health record for effective utilisation in the clinical process, remains an open problem.

Reimbursement issues – economic evaluations

In most European countries, lack of reimbursement models and the complexity of the health service systems have prevented the widespread use of digital health services. Firstly, current reimbursement models are often not applicable to digital health services, which may require bundled or lump sum payments, and should be part of a pathology-specific care pathway. Secondly, reimbursement models for new types of health services that can only be performed by digital health tools are lacking. In addition, contemporary reimbursement classically covers only the costs directly related to patient care, without remunerating the start-up investment needed to establish and prove new healthcare strategies. Reimbursement issues may take place at multiple levels ranging from the suppliers of digital health services or products (with implications for development, operation, support and innovation of technologies) to healthcare clinics and specialists using digital health as a complement to their traditional services.

Addressing the challenges/barriers for digital health deployment

As described in the ESC e-health position statement, ensuring implementation of innovative digital healthcare delivery programmes into the current healthcare system is challenging.¹³ It often necessitates extensive workflow redesign, which is why it frequently fails to be successfully adopted.

Despite future opportunities related to the latest information and communication technologies

innovations (i.e. 5G wireless communication network, enhanced artificial intelligence computational power, virtual and enhanced reality), overcoming the current barriers represents the initial step to achieve digital health deployment in daily clinical routine.⁵⁷ Accordingly, in the remaining part of this section, some key concepts on how to tackle the contemporary challenges for large-scale digital health deployment will be provided (see also Figure 1).

The role of patient education programmes

Patient education by dedicated professionals about the benefits of digital healthcare is a prerequisite to tackle the perception that this novel type of service would be inferior. The efficacy of patient education programmes on the uptake and use of web-based, digital health interventions has indeed been shown previously in cardiovascular disease patients.⁵⁸ Digital health programme components should be developed applying a user-centric approach and taking into account user (i.e. patient) needs and preferences from the first prototype to the final end-product stage.⁵⁹ Product simplicity and patient feasibility/usability should be prioritised, considering also specific group needs (e.g. elderly, culturally and linguistically diverse patients with lower health literacy), together with possible patient-specific customisation.

The role of digital health workflow redesign

Achieving improved digitisation of healthcare in the hospitals, in particular for cardiovascular care, represents the first necessary prerequisite to improve physician–patient relationships, by maintaining the physician's time to serve primarily as a diagnostician and educator instead of doing actions that could be handled through automated systems. By better individualising diagnostics and treatments, facilitating patient data retrieval, simplifying real-world monitoring, and providing evidence-based guidance at the point of need, digital technologies have this potential, thus constituting the basis to build on further solutions to improve patient empowerment.⁶⁰

Integration of digital health in routine care implies shifting roles and responsibilities for healthcare personnel.⁶¹ Specific training programmes for all caregivers and medical students should be developed, to assist them in understanding the new service models resulting from digital health deployment, related capabilities and limitations. In addition, these programmes would ideally also aid them in the application and adoption of the new technology-based care. This will encourage healthcare professionals to invest time in redesigning contemporary healthcare pathways (based on clinical

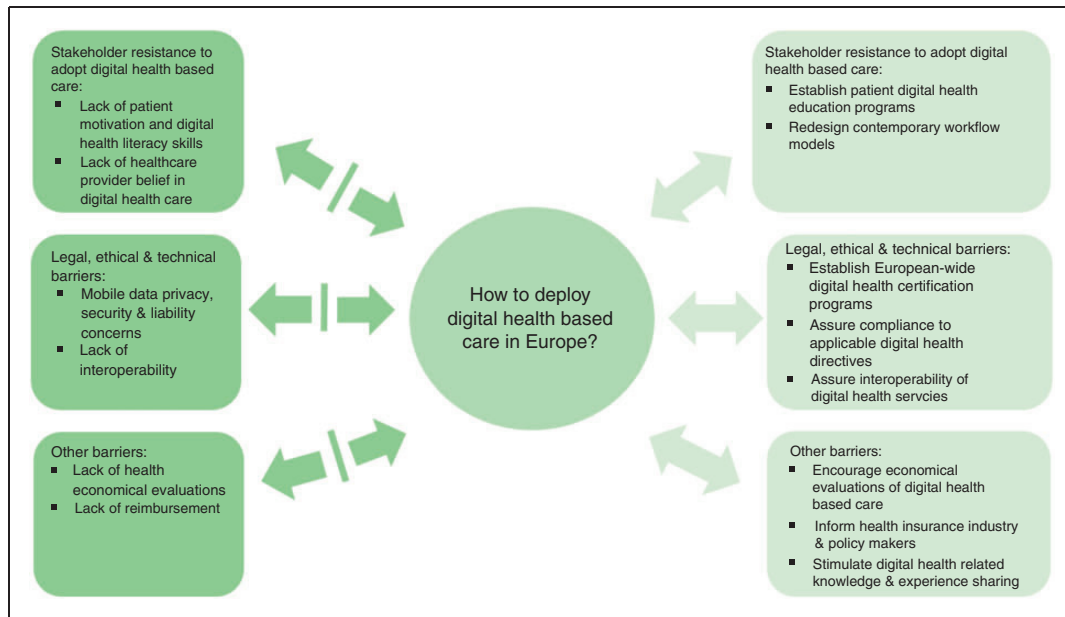


Figure 1. Key messages related to digital health-based care in cardiovascular medicine. The left side of the figure depicts the main barriers to large-scale deployment, the right side of the figure suggests key measures on how to address these barriers.

evidence and cost-effectiveness data) before implementing novel digital healthcare strategies, thus reducing the risk of creating duplicates instead of improving care. Scientifically founded open fora would enable all stakeholders involved to share experiences and challenges/barriers identified during digital health adoption and accelerate mutual learning and knowledge sharing. Upfront clear definitions of the digital health intervention content and its primary goal would simplify successful implementation. Specific, relevant, attainable and measurable digital health programme quality indicators should be defined and (re-)assessed repetitively to monitor success and convince healthcare providers resistant to adopt.⁶²

The role of uniform, European-wide digital health legislation

In Europe, results from a public consultation launched in 2014⁶³ stressed the importance of strong privacy and security tools to build users' trust, as well as to provide more patient safety and transparency of information, by means of certification schemes or quality labelling of lifestyle and wellbeing apps.

Several EU legislations, among others, are producing impact on digital health:

Directive 93/42/EEC and following amendments⁶⁴ define software for medical purposes, potentially including m-health apps, as a medical device and as such it is intended to be validated according to the

state of the art taking into account the principles of development life cycle, risk management, validation and verification. This directive will be superseded, and made even more stringent, in the spring of 2020, as the new EU Regulation 2017/745, approved and published on 5 May 2017 in the *Official Journal of the European Union*, will have to be applied in all EU countries.

General Data Protection Regulation 2016/679 (known as GDPR),⁶⁵ applicable as from 25 May 2018, harmonises data privacy laws across Europe to protect and empower all EU citizens data privacy with extended jurisdiction (it applies to all companies processing the personal data of subjects residing in the EU), extending the concept of personal data, and extending liability to all data 'processors'.

Privacy and Electronics Communication Directive 2002/58/EC and following amendments⁶⁶ (known as ePrivacy directive) deals with a number of important issues such as confidentiality of information, treatment of traffic data, spam and cookies, underscoring the importance of data minimisation and purpose limitation, and the necessity for data anonymisation and restrictive data authorisation access.

Compliance of digital health applications to the applicable EU legislation should be assured and reported transparently. Liability hazards inherent to digital health services should be explored and addressed profoundly upfront in order to ensure the reliability of these services.

The role of data standardisation and interoperability assurance

Interoperability allows two or more applications to communicate effectively without compromising the content of the transmitted data. Interoperability makes it possible to share patient health information among healthcare professionals and organisations, allowing a seamless care environment and aiming at the continuity of care in all patient contexts and across the spectrum of the caregivers and their respective environments.⁶⁷ Several previous international experiences were aimed at finding the basis for interoperability assurance. In 2005, the ESC launched the Cardiology audit and Registration Data Standard (CARDS) project, with the aim of collecting shared definitions of core data elements within health information systems.⁶⁸ Initiatives supporting the realisation of interoperable digital health services will potentiate its large-scale deployment.

The role of digital health industry

Due to the involvement of personal data and confidential information, large-scale deployment and utilisation in clinical practice of digital health solutions greatly depend on the trustworthiness of the provider/developer. It has to be a priority for stakeholders in the digital health industry to guarantee the privacy and safety of their solutions, as well as to describe clearly accuracy and efficacy claims, providing documentation and scientific literature in support, and being transparent about clinical evidence and unexpected failures, safety notices, alerts or recalls (also related to software).⁶⁹ In the field of m-health apps, app stores (i.e. Apple app store, GooglePlay) should increase controls and verification before publishing an app with higher transparency about their process, and improving app categorisation, i.e. creating a specific category for approved 'software as medical device', or highlighting apps published by developers that adhere to specific codes of conduct.

The role of the health insurance industry

Information on the costs and effects of digital health interventions is needed to document value for money and to support decision-making, but also to form the basis for developing business models and to facilitate payment systems to support large-scale implementation. In the absence of robust evidence, decision-makers may be more reluctant to support the implementation of digital health services.⁷⁰ It is recommended that more economic evaluations and implementation research are being conducted to add to the

evidence base and for use in modelling studies. In case sufficient evidence regarding the cost-efficiency of digital healthcare programmes is established, efforts to convince the health insurance industry to support and/or incentivise those programmes financially are justified. However, before interventions and technologies can be shown to be cost-effective, they must have positive impact on meaningful health outcomes or experiences of care in the first place.

The role of patient organisations

Patient organisations provide support, often peer led, for patients and their families affected with cardiovascular disease. In 2009, the British Cardiac Patients Association emphasised the key areas they believe are fundamental in the provision of effective care.⁷¹ Patients want to be treated holistically, and not to have symptoms managed independent of other needs. Patients sometimes have difficulty understanding why a treatment that they read about may not be suitable for them, so providing information in a simple way at every step of the patient journey must be considered. Any digital healthcare-related action which facilitates these goals is highly rated by patients and their families. In addition, informed patients may help in the early detection of (recurrent) disease. The quality of patient experience must become the foundation of co-design, development and delivery of digital health interventions.⁷² Both local and national cardiovascular patient organisations can help to voice the patients' needs and help ensure that digital health services are answering their needs, and are in line with their preferences for care and access to care.

The role of professional organisations

As evidenced by the contributions to this position paper, national and European-wide professional organisations, such as the ESC through its multiple bodies, are committed to the different facets of digital healthcare delivery. They have a pivotal cross-fertilising role in sharing expertise and supporting colleagues to establish better services. By collaborative efforts in creating professional guidelines and/or other guiding position documents, they can play a critical role in ensuring the flourishing of digital healthcare delivery in Europe and worldwide. As an example, the organisation of specific digital health sessions at the ESC annual congress (under the digital health track) enables many interested stakeholders to increase their knowledge by listening to experts in the field. This type of activity will continue to expand, under the supervision of the Digital Health Committee and the board, working with the associations and working groups.

Key points on how to tackle the contemporary digital health challenges in cardiology

This paragraph is intended to provide possible suggestions to be explored in the upcoming years to pave the way for further development of the concept of digital healthcare and related challenges in cardiology:

- The inclusion of digital health-related topics in the current ESC Cardiology Core curriculum.⁷³
- All ESC bodies (associations, councils, working groups) with an interest in the practical application of digital healthcare delivery should be encouraged, under the coordination of the ESC Digital Health Committee, to develop specific courses/educational material to instruct cardiologists on how to apply this novel care strategy in practice. Ideally, in the medium to long term digital health should be incorporated in the official ESCeL e-learning platform to ensure widespread reach of its educational content.
- Given the future role of digital healthcare delivery in cardiology, there is a need for the establishment of ESC endorsed certification programmes (i.e. similar to EACVI TTE, or CMR certification programmes) with the aim to train and certify cardiologists willing to apply digital health in their institution.
- Relevant patient organisations (both at a local/national and European level) should be involved in all digital health-related activities, to ensure their input from the earliest phase of development, through the widespread deployment. This is likely to increase the acceptability of the innovation to the final digital healthcare consumer (i.e. the cardiac patient).
- The presence of advocating healthcare professional representatives in specific task forces or stakeholder groups at the level of discussion, forum, or political decision support needs to be pursued and supported, to give visibility to medical associations and to facilitate the compliance of digital health-related directives and/or regulations into clinical practice, thus balancing and complementing industry presence in such bodies. The ESC representation in the e-Health stakeholder group of the European Commission⁷⁴ and its m-health working group are examples of how this could be achieved.
- Scientific research in the field of digital health in the cardiology domain, especially when combining both clinical and socioeconomic analyses, should be stimulated and supported, to increase the evidence base for possible future reimbursement for specific digital health solutions. In particular, research focusing on specific populations (e.g. patients with low health literacy skills and/or low socioeconomic status, or elderly groups) to assess the impact and risk of

social inequalities, and possible risk mitigation strategies, is further encouraged. Lessons learned from previous European and large-scale deployment projects that implemented and assessed the impact of innovative healthcare services for remote monitoring of patients with chronic conditions (e.g. United4Health, Momentum)^{75,76} should guide us in the way ahead.

Conclusion

Digital health-based healthcare models have been introduced recently in cardiology due to the advent of innovations in telecommunication technologies. They enable cardiac patients to take a more active role in their own care and have the potential to improve contemporary clinical care pathways considerably. This ESC WG e-Cardiology Position Paper, developed in close collaboration with the ESC Digital Health Committee, EAPC, the European Heart Rhythm Association (EHRA), the European Association of Cardiovascular Imaging (EACVI), the Heart Failure Association (HFA), ACCA, the European Association of Percutaneous Cardiovascular Interventions (EAPCI), ACNAP and the Council on Hypertension (CHT) calls for action. It provides the reader with a brief overview of available digital health applications in different cardiovascular disease settings. It identifies relevant barriers currently impeding large-scale digital health deployment in Europe. In addition, it summarises how these challenges could be tackled and describes some specific key points that could facilitate the flourishing of digital health in cardiology in the future.

Author contribution

IF, EGC and PD contributed to the conception and design of the manuscript. SA, JB, AB, MC, JC, ND, PD, TH, FK, GK, EL, PL, PM, LN, GF, EP MT and EV contributed to the acquisition and/or analysis and/or interpretation of data for the work. IF, EGC, PD, ND, PD, TH, FK, GK, EL, PL, PM, LN, GF, EP MT and EV drafted the manuscript. SA, JB, AB, MC and JC critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work ensuring integrity and accuracy.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Permissions information

The authors declare that all illustrations and figures in the manuscript are entirely original and do not require reprint permission.

References

1. Timmis A, Townsend N, Gale C, et al.; the Atlas Writing Group. European Society of Cardiology: Cardiovascular Disease Statistics 2017. *Eur Heart J* 2018; 39: 508–579.
2. Chestnov O. World Health Organization. *Noncommunicable diseases and mental health*. www.who.int/nmh/events/ncd_action_plan/en/ (accessed 19 November 2016).
3. Kotseva K, Wood D, De Bacquer D, et al.; EUROASPIRE Investigators. EUROASPIRE IV: A European Society of Cardiology survey on the lifestyle, risk factor and therapeutic management of coronary patients from 24 European countries. *Eur J Prev Cardiol* 2016; 23: 636–648.
4. Gandapur Y, Kianoush S, Kelli HM, et al. The role of mHealth for improving medication adherence in patients with cardiovascular disease: a systematic review. *Eur Heart J Qual Care Clin Outcomes* 2016; 2: 237–244.
5. Ibanez B, James S, Agewall S, et al.; ESC Scientific Document Group. 2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation: the Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC). *Eur Heart J* 2018; 39: 119–177.
6. Roffi M, Patrono C, Collet JP, et al. 2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: Task Force for the Management of Acute Coronary Syndromes in Patients Presenting without Persistent ST-Segment Elevation of the European Society of Cardiology (ESC). *Eur Heart J* 2016; 37: 267–315.
7. Montalescot G, Sechtem U, Achenbach S, et al.; ESC Committee for Practice Guidelines. 2013 ESC Guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. *Eur Heart J* 2013; 34: 2949–3003.
8. Ruano-Ravina A, Pena-Gil C, Abu-Assi E, et al. Participation and adherence to cardiac rehabilitation programs. A systematic review. *Int J Cardiol* 2016; 223: 436–443.
9. Clark A, King-Shier K, Duncan A, et al. Factors influencing referral to cardiac rehabilitation and secondary prevention programs: a systematic review. *Eur J Prev Cardiol* 2012; 20: 692–700.
10. Frederix I, Vanhees L, Dendale P, et al. A review of telerehabilitation for cardiac patients. *J Telemed Telecare* 2015; 21: 45–53.
11. Piepoli MF, Corrà U, Dendale P, et al. Challenges in secondary prevention after acute myocardial infarction: a call for action. *Eur J Prev Cardiol* 2016; 23: 1994–2006.
12. Pagoto S and Bennett GG. How behavioral science can advance digital health. *Transl Behav Med* 2013; 3: 271–276.
13. Cowie MR, Bax J, Bruining N, et al. e-Health: a position statement of the European Society of Cardiology. *Eur Heart J* 2016; 37: 63–66.
14. European Society of Cardiology. *Digital Health Committee composition*. www.escardio.org/The-ESC/Governance/ESC-Committees/esc-digital-health-committee (accessed 8 August 2018).
15. Pagliari C, Sloan D, Gregor P, et al. What is eHealth: a scoping exercise to map the field. *J Med Internet Res* 2005; 7: e9.
16. Frederix I, Vandenberg T, Janssen L, et al. eEduHeart I: A multicenter, randomized, controlled trial investigating the effectiveness of a cardiac web-based eLearning platform – rationale and study design. *Cardiology* 2017; 136: 157–163.
17. Inglis SC, Clark RA, McAlister FA, et al. Which components of heart failure programmes are effective? A systematic review and meta-analysis of the outcomes of structured telephone support or telemonitoring as the primary component of chronic heart failure management in 8323 patients: Abridged Cochrane Review. *Eur J Heart Fail* 2011; 13: 1028–1040.
18. Neubeck L, Cartledge S, Dawkes S, et al. Is there an app for that? Mobile phones and secondary prevention of cardiovascular disease. *Curr Opin Cardiol* 2017; 32: 567–571.
19. Parati G, Stergiou GS, Asmar R, et al.; ESH Working Group on Blood Pressure Monitoring. European Society of Hypertension guidelines for home blood pressure monitoring. *J Hum Hypertens* 2010; 24: 779–785.
20. Parati G, Stergiou GS, Asmar R, et al.; ESH Working Group on Blood Pressure Monitoring. European Society of Hypertension guidelines for blood pressure monitoring at home: a summary report of the Second International Consensus Conference on Home Blood Pressure Monitoring. *J Hypertens* 2008; 26: 1505–1530.
21. Parati G, Omboni S, Albini F, et al.; TeleBPCare Study Group. Home blood pressure telemonitoring improves hypertension control in general practice. The TeleBPCare study. *J Hypertens* 2009; 27: 198–203.
22. Omboni S, Gazzola T, Carabelli G, et al. Clinical usefulness and cost effectiveness of home blood pressure telemonitoring: metaanalysis of randomized controlled studies. *J Hypertens* 2013; 31: 455–467.
23. Milani RV, Lavie CJ, Bober RM, et al. Improving hypertension control and patient engagement using digital tools. *Am J Med* 2017; 130: 14–20.
24. Parati G, Torlasco C, Omboni S, et al. Smartphone applications for hypertension management: a potential game-changer that needs more control. *Curr Hypertens Rep* 2017; 19: 48.
25. Wolf A, Fors A, Ulin K, et al. An e-Health diary and symptom-tracking tool combined with person-centered care for improving self-efficacy after a diagnosis of acute coronary syndrome: a substudy of a randomized controlled trial. *J Med Internet Res* 2016; 18: e40.

26. Saner H and Van der Velde E. e-Health in cardiovascular medicine: a clinical update. *Eur J Prev Cardiol* 2016; 23: 5–12.
27. Frederix I, Hansen D, Coninx K, et al. Medium-term effectiveness of a comprehensive internet-based and patient-specific telerehabilitation program with text messaging support for cardiac patients: randomized controlled trial. *J Med Internet Res* 2015; 17: e185.
28. Frederix I, Solmi F, Piepoli MF, et al. Cardiac telerehabilitation: a novel cost-efficient care delivery strategy that can induce long-term health benefits. *Eur J Prev Cardiol* 2017; 24: 1708–1717.
29. Kraal JJ, Van den Akker-Van Marle ME, Abu-Hanna A, et al. Clinical and cost-effectiveness of home-based cardiac rehabilitation compared to conventional, centre-based cardiac rehabilitation: results of the FIT@Home study. *Eur J Prev Cardiol* 2017; 24: 1260–1273.
30. Inglis SC, Clark RA, Dierckx R, et al. Structured telephone support or non-invasive telemonitoring for patients with heart failure. *Cochrane Database Syst Rev* 2015; 10: CD007228.
31. Landolina M, Perego GB, Lunati M, et al. Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study. *Circulation* 2012; 125: 2985–2992.
32. Böhm M, Drexler H, Oswald H, et al. Fluid status telemedicine alerts for heart failure: a randomized controlled trial. *Eur Heart J* 2016; 37: 3154–3163.
33. Hindricks G, Taborsky M, Glikson M, et al. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. *Lancet* 2014; 384: 583–590.
34. Morgan JM, Dimitrov BD, Gill J, et al. Rationale and study design of the REM-HF study: remote management of heart failure using implanted devices and formalized follow-up procedures. *Eur J Heart Fail* 2014; 16: 1039–1045.
35. ESC. Education. www.escardio.org/Education (accessed 17 March 2018).
36. Educator for Heart.org. <https://www.heart.org/en/professional/educator> (accessed 17 March 2018).
37. Piotrowicz E, Zieliński T, Bodalski R, et al. Home-based telemonitored Nordic walking training is well accepted, safe, effective and has high adherence among heart failure patients, including those with cardiovascular implantable electronic devices – a randomized controlled study. *Eur J Prev Cardiol* 2015; 22: 1368–1377.
38. Halcox J, Wareham K, Cardew A, et al. Assessment of remote heart rhythm sampling using the AliveCor heart monitor to screen for atrial fibrillation: the REHEARSE-AF Study. *Circulation* 2017; 136: 1784–1794.
39. Kotecha D, Chua WWL, Fabritz L, et al.; European Society of Cardiology (ESC) Atrial Fibrillation Guidelines Taskforce, the CATCH ME consortium and the European Heart Rhythm Association (EHRA). European Society of Cardiology smartphone and tablet applications for patients with atrial fibrillation and their health care providers. *Europace* 2018; 20: 225–233.
40. Ware P, Bartlett SJ, Paré G, et al. Using e-Health technologies: interests, preferences, and concerns of older adults. *Interact J Med Res* 2017; 6: e3.
41. Torrent-Sellens J, Díaz-Chao A, Soler-Ramos I, et al. Modelling and predicting e-Health usage in Europe: a multidimensional approach from an online survey of 13,000 European Union internet users. *J Med Internet Res* 2016; 18: e188.
42. Watkins I and Xie B. e-Health literacy interventions for older adults: a systematic review of the literature. *J Med Internet Res* 2014; 16: e225.
43. Xesfingi S and Vozikis A. e-Health literacy: in the quest of the contributing factors. *Interact J Med Res* 2016; 5: e16.
44. The European Commission. *e-Health Action Plan 2012–2020 – Innovative healthcare for the 21st century*. 2012. http://ec.europa.eu/health/sites/health/files/e-Health/docs/com_2012_736_en.pdf (accessed 17 March 2018).
45. Rai A, Chen L, Pye J, et al. Understanding determinants of consumer mobile health usage intentions, assimilation, and channel preferences. *J Med Internet Res* 2013; 15: e149.
46. Richtering SS, Hyun K, Neubeck L, et al. e-Health literacy: predictors in a population with moderate-to-high cardiovascular risk. *JMIR Hum Factors* 2017; 4: e4.
47. Burke LE, Ma J, Azar KM, et al.; American Heart Association Publications Committee of the Council on Epidemiology and Prevention, Behavior Change Committee of the Council on Cardiometabolic Health, Council on Cardiovascular and Stroke Nursing, Council on Functional Genomics and Translational Biology, Council on Quality of Care and Outcomes Research, and Stroke Council. Current science on consumer use of mobile health for cardiovascular disease prevention. A scientific statement from the American Heart Association. *Circulation* 2017; 136: 1.
48. Kontos E, Blake KD, Chou W-YS, et al. Predictors of eHealth usage: insights on the digital divide from the Health Information National Trends Survey 2012. *J Med Internet Res* 2014; 16: e172.
49. Schaeffer D, Berens EM and Vogt D. Health literacy in the German population. *Dtsch Arztebl Int* 2017; 114: 53–60.
50. Sørensen K, Pelikan JM, Rothlin F, et al. Health literacy in Europe: comparative results of the European health literacy survey (HLS-EU). *Eur J Public Health* 2015; 25: 1053–1058.
51. Melchiorre MG, Lamura G and Barbabella F. ICARE4EU Consortium. eHealth for people with multimorbidity: results from the ICARE4EU project and insights from the “10 e’s” by Gunther Eysenbach. *PLoS One* 2018; 13: e0207292.
52. Weiss D, Rydland HT, Øversveen E, et al. Innovative technologies and social inequalities in health: a scoping review of the literature. *PLoS One* 2018; 13: e0195447.
53. Villalba-Mora E, Casas I, Lupianez-Villaneuva F, et al. Adoption of health information technologies by physicians for clinical practice: the Andalusian case. *Int J Med Informat* 2015; 84: 477–485.

54. Yang YT and Silverman RD. Mobile health applications: the patchwork of legal and liability issues suggests strategies to improve oversight. *Health Aff (Millwood)* 2014; 33: 222–227.
55. Chan M, Esteve D, Fourniols JY, et al. Smart wearable systems: current status and future challenges. *Artif Intell Med* 2012; 56: 137–156.
56. Bruining N, Caiani E, Chronaki C, et al. Acquisition and analysis of cardiovascular signals on smartphones: potential, pitfalls and perspectives. By the Task Force on the e-Cardiology Working Group of European Society of Cardiology. *Eur J Prev Cardiol* 2014; 21: 4–13.
57. Bruining N, Barendse R and Cummins P. The future of computers in cardiology: ‘the connected patient’? *Eur Heart J* 2017; 38: 1781–1794.
58. Schweier R, Romppel M, Richter C, et al. Dissemination strategies and adherence predictors for web-based interventions-how efficient are patient education sessions and email reminders? *Health Educ Res* 2016; 31: 384–394.
59. Roesler V, Binotto AP, Iochpe C, et al. Improving preventive healthcare with a user-centric mobile tele-monitoring model. *Stud Health Technol Inform* 2015; 216: 648–652.
60. Steinhubl SR and Topol EJ. Moving from digitalization to digitization in cardiovascular care: why is it important and what can it mean for patients and providers? *J Am Coll Cardiol* 2015; 66: 1489–1496.
61. McLean S, Protti D and Sheikh A. Tele-Healthcare for long term conditions. *BMJ* 2011; 342: d120.
62. Frederix I, Dendale P and Sheikh A. FIT@Home editorial: Supporting a new era of cardiac rehabilitation at home? *Eur J Prev Cardiol* 2017; 24: 1485–1487.
63. European Commission. *mHealth in Europe: Preparing the ground – consultation results published*. <https://ec.europa.eu/digital-single-market/en/news/mhealth-europe-preparing-ground-consultation-results-published-today> (accessed 17 March 2018).
64. Official Journal of the European Union. *Directive 2007/47/EC of the European Parliament and of the council*. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:en:PDF> (accessed 17 March 2018).
65. Official Journal of the European Union. *Regulation (EU) 2016/679 of the European parliament and of the council*. <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN> (accessed 17 March 2018).
66. EUR-Lex. *Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector*. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004L0052> (accessed 20 March 2018).
67. Moreno-Conde A, Moner D, Dimas da Cruz W, et al. Clinical information modeling processes for semantic interoperability of electronic health records: systematic review and inductive analysis. *J Am Med Inform Assoc* 2015; 22: 925–934.
68. Flynn MR, Barrett C, Cosío FG, et al. The Cardiology Audit and Registration Data Standards (CARDS), European data standards for clinical cardiology practice. *Eur Heart J* 2005; 26: 308–313.
69. Fraser AG, Butchart EG, Szymański P, et al. The need for transparency of clinical evidence for medical devices in Europe. *Lancet* 2018; 392: 521–530.
70. Bergmo TS. How to measure costs and benefits of e-health interventions: an overview of methods and frameworks. *J Med Internet Res* 2015; 17: e254.
71. British Cardiac Patients Association. *Cardiovascular Patients’ Bill of Rights Spring 2009*. <http://bcpa.uk/pdf/BillOfRights.pdf> (accessed 2 December 2017).
72. Barello S, Triberti S, Graffigna G, et al. eHealth for patient engagement: a systematic review. *Front Psychol* 2016; 6: 2013.
73. Gillebert TC, Brooks N, Fontes-Carvalho R, et al. ESC core curriculum for the general cardiologist (2013). *Eur Heart J* 2013; 34: 2381–2411.
74. European Commission. *New Members eHealth Stakeholder Group*. <https://ec.europa.eu/digital-single-market/en/news/new-members-ehealth-stakeholder-group-have-been-selected> (8 August 2018).
75. United4Health. *Telehealth in practice. Care delivery models from 14 regions in Europe*. <http://united4health.eu/wp-content/uploads/2016/01/U4H-Brochurev1.0.pdf> (10 August 2018).
76. Momentum. *European Momentum for Mainstreaming Telemedicine Deployment in Daily Practice*. <http://www.telemedicine-momentum.eu/> (10 August 2018).