

# e-Health: a position statement of the European Society of Cardiology

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## Introduction

e-Health encompasses the use of information and communication technologies (ICTs) in the support of health and health-related activity.<sup>1</sup> It can be subdivided into several domains, listed in *Table 1*.<sup>2</sup>

e-Health has the potential to provide innovative solutions to health issues, and is often viewed by politicians and healthcare professionals as a key ‘enabling’ technology to improve care and the experience of care for the those living with chronic conditions, particularly at a time of constrained healthcare funding.

Behind all of this stands the individual/citizen/patient/customer, who is increasingly familiar with ICT and expects to find it supporting modern healthcare delivery, facilitating more personalized and person-centred care at the right time and in the right place.

In theory, technological innovation should bring better inter-professional co-operation, information sharing, decision support, and flexibility to the healthcare system. However, there are important societal and professional constraints that reduce the impact of such innovation, including legal, ethical, and data protection issues. Healthcare professionals may be resistant to such innovation, particularly if the technologies are considered to be ‘solutions seeking a problem’ and where the evidence for the impact on quality of care is seen as less than robust. Indeed, ensuring proper integration of new technologies into the healthcare system is often difficult, requiring process redesign or ‘disruption’.<sup>6</sup> Regulatory bodies, reimbursement authorities, and national and international political bodies often find it difficult to react quickly, or consistently, to this rapidly changing area.

The European Union has an e-health action plan for 2012–2020, which states that the promise of ICT to increase efficiency, improve quality of life, and unlock innovation in health markets remains largely unfulfilled.<sup>7</sup> Initiatives such as large-scale pilot projects (e.g. European patients smart open services), the 2011 Directive on the Application of Patients’ Rights in Cross Border Healthcare, and

the establishment of an e-health network have made some difference but the Action Plan identified several barriers to widespread adoption of e-health, including:

- Lack of awareness of, and confidence in, e-health solutions
- Lack of inter-operability
- Limited large-scale evidence of the cost-effectiveness
- Lack of legal clarity for health and well-being mobile applications and the lack of transparency regarding the utilization of data collected, including data that crosses international boundaries
- Inadequate, or fragmented, legal frameworks
- Lack of reimbursement
- Regional differences in accessing ICT services, with limited access in deprived areas

## Aims

The European Society of Cardiology (ESC) is involved with e-health on many different levels. Its members deal with the changes in practice that ICT innovation brings, including electronic medical records, e-referrals or e-prescribing, teleconsultation, and telemonitoring. The Society uses electronic collection of data in its programme of disease and practice registries, the EuroObservational Research Programme, and is involved in pan-European research projects on semantic inter-operability.

This document reflects the current position of the ESC on e-health. It highlights the key aspects relevant to cardiovascular health and healthcare delivery to individuals with, or at risk of, cardiovascular disease. This position statement originated from discussions between members of the Board of the ESC, the Working Group on e-cardiology, and the Cardiovascular Roundtable that took place during a workshop in April 2014. It outlines the medium-term ‘roadmap’ of how the ESC will mobilize its members and Constituent Bodies (National Cardiac Societies, Speciality

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**Table 1** The domains of e-health, involving healthcare administration and support, education, healthcare delivery, and research

- (1) Telemedicine and telecare (including disease management services, remote patient monitoring, teleconsultations, and homecare)<sup>3</sup>
- (2) Clinical information systems (electronic medical records, decision support and monitoring of clinical and institutional practice)
- (3) Integrated regional and national information networks and associated e-referrals and e-prescribing
- (4) Disease registries and other non-clinical systems used for education, public health, patient/disease-related behaviour, and healthcare management
- (5) 'Mobile' health (m-health) including mobile applications ('Apps'): medical and public health practice supported by mobile technologies delivering health information, screening patients, monitoring physiological signs, providing direct care and patient education (sometimes considered part of telemedicine,<sup>3</sup> but increasingly less medicalized)
- (6) 'Personalized' health (p-health): wearable or implantable micro- and nano-technologies with sensors and/or therapy delivery devices to help facilitate health and social care decision making and delivery (including fall detectors, implantable insulin pumps, defibrillator vests, etc.).
- (7) 'Big Data'—large-scale integration and analysis of heterogeneous data sources, usually of high volume (amount of data), velocity (speed of data in and out), and variety (range of data types and source)<sup>4</sup>, ideally linked at the individual person level to provide a more holistic view of a patient/individual and shed light on social and environmental factors that may influence health.<sup>5</sup>

Associations, Working Groups, and Councils) and seek to achieve broad and meaningful engagement and consensus with stakeholders, recognizing the challenges and opportunities that ICT development will bring. No individual cardiologist or clinical department can develop the appropriate expertise to tackle the numerous issues that surround e-health, but the ESC can support cardiologists as they tackle these issues in day-to-day practice.

## The European Society of Cardiology vision

The vision of the ESC is to play a pro-active role in all aspects of the e-health agenda, helping to develop, assess, and implement effective ICT innovations in the support of cardiovascular health and health-related activity across Europe. This vision will be realized through the action plan below:

### The action plan

- To facilitate wider implementation of e-health.
- To educate and train ESC members in the appropriate use of e-health.
- To play an active role in discussions regarding regulation and quality control of ICT technologies, including (where appropriate) setting benchmark quality standards for relevant technologies.
- To play an active role in the societal and political discussions regarding data security and confidentiality issues, recognizing the

geographical variation in legal constraints. This includes appropriate patient access to data.

- To support research into the development, evaluation, and implementation of e-health technologies, with an emphasis on establishing the clinical and cost-effectiveness of such innovation, and including the patient perspective. The actions patients take in response to data collected requires particular scrutiny (especially where this action is not supervised by healthcare professionals).
- To promote policy dialogue related to e-health at local, national, and international level with all relevant stakeholders, including payers. Reimbursement issues often delay the implementation of e-health solutions, even where the evidence base for clinical and cost-effectiveness/sustainability is secure.
- To provide a resource for citizens in the member countries to assist them in assessing the potential benefit and risk of e-health applications in cardiovascular disease prevention, diagnosis, and treatment.

## Specific issues

### m-health and p-health

The EU recently issued a consultation document on m-health.<sup>8</sup> It highlighted the pace of change—with nearly 100 000 mHealth Apps already available, and the top 20 free sports, fitness, and health Apps having been downloaded >230 million times. It estimated that by 2017, >3 billion people will own a smartphone and half of them will be using Apps. Currently, there are no clear rules on the difference between a medical device (diagnostic or therapeutic) and a 'lifestyle and well-being' App. It is unclear as to whether there are risks associated with health Apps, and what liability developers or service providers might have. More broadly, there are concerns about use of the data, the lack of stakeholder awareness of the legal requirements applicable to Apps, and the lack of inter-operability between available solutions. Health care professionals are also uncertain of the value of such technologies, do not know how to assess available 'solutions', and are reluctant to integrate such systems into their decision making. Lack of clarity on data protection issues, confidentiality, and legal liability are often raised as reasons for lack of implementation. In addition, lack of reimbursement for new technologies is a major barrier to appropriate implementation.

There is no global approach to regulation of these new technologies—with clear differences between the FDA and EU agencies. Additionally, professional organizations have largely ignored this rapidly expanding aspect of health and lifestyle decision making.

Similar issues arise with wearable technologies, including bracelets or watches that collect physiological data and integrate them with other information systems. In theory, these may help promote health and healthy lifestyle choices, and assist in monitoring of exercise prescriptions and rehabilitation programmes.

Those developing new m-health or p-health technologies need not have any medical input to their development programmes, and thus may provide sub-optimal (or even harmful) 'solutions' that patients or citizens may assume are of proven benefit. There is some consumer protection from unsubstantiated claims of health benefit, but they may be misled into purchasing a technology with less benefit than advertised. The boundaries between a 'patient'

and a 'consumer' have become increasingly blurred, as have the responsibilities of the healthcare team.

The ESC is enthusiastic about its role as a key stakeholder in the development of ICT solutions. Closer working between all stakeholders—consumer and patient organizations, health professionals and health organisations, public authorities, App developers, telecommunication service providers, mobile device manufacturers, and others—should optimize the appropriate development and implementation of new solutions to health and healthcare needs.

## Political advocacy

The potential for e-health to transform health and healthcare has been clearly stated by political bodies, including the European Commission.<sup>7</sup> A previous Commission Vice-President, Neelie Kroes, is on record as stating that 'm-health will reduce costly visits to hospitals, help citizens take charge of their own health and well-being, and move towards prevention rather than cure'. It is therefore vital that the ESC, representing >80 000 cardiology professionals across Europe and the Mediterranean, engages with advocacy on e-health and provides a valuable source of advice and testing for such systems.

## Key European Society of Cardiology deliverables in e-health

The ESC delivers its vision largely through investment in research, training, education, and advocacy. Increasingly, it also collects data on healthcare performance and variation across its geographical area, and is involved in advocacy at all levels on issues related to cardiovascular health and disease.

## Education and training

Education is at the core of the ESC mission to reduce the burden of cardiovascular disease in Europe.

Through its annual ESC Congress and the meetings of its constituent organizations, it will seek to ensure all relevant aspects of e-health are included in the programmes in the form of lectures, workshops, seminars, and 'hands on' sessions. It will also seek to engage with relevant stakeholders for such meetings, including those providing ICT solutions. The society and its constituent organizations already make much use of its websites for interactive education for healthcare professionals, and also for patients. This will be further strengthened.

Through updating of its core curriculum and syllabus, the ESC will ensure e-health is a key component of the knowledge and skills acquired by its members in practice. Such information will be included in its textbooks, courses, and e-learning platforms.

Issues of patient confidentiality, data protection, and liability will be an integral part of the education and training on e-health.

The ESC will also seek to work with other professional organizations to ensure access to all relevant skills and knowledge in the area of e-health.

## Regulation and quality control

Although not moving to endorsement of particular e-health solutions, the ESC will explore methods to enable its members and citizens of its represented countries to gain access to appropriate assessments of new ICT solutions. This may include reviews of

technologies, including Apps, by its members. In addition, it will seek to benchmark standards for the assessment of the healthcare impact of ICT solutions, and of data handling and processing.

## Legal and ethical issues

The ESC will seek to engage in active dialogue with all relevant stakeholders on the challenging area of data security, confidentiality, and legal liability related to e-health. The 56 national member societies will be supported in such work by the ESC, particularly as the data and legal issues often vary markedly between countries.

## Research and development

As the ESC becomes more involved in commissioning research, it will seek to include e-health as part of its core research activities. In addition, it will support and encourage its members to become more involved in research in this area e.g. development of solutions, inter-operability, data standards, user and professional interfaces, data linkage, information processing, and assessment of health and healthcare impact and value for money.

## Advocacy

The ESC will seek to engage pro-actively with the relevant stakeholders in e-health, including those with or at risk of cardiovascular disease, healthcare professionals, national professional organizations, patient organizations, the European Commission, and those developing e-health solutions. It will also take part in policy development in this area with the relevant organizations.

## Roadmap

In support of the above action plan, the ESC has drawn up a roadmap, shown in *Table 2*.

**Table 2** Roadmap for deliverables for the European Society of Cardiology e-health action plan

- Develop a Glossary of eHealth terms: end 2015
- Publish a position paper as a basis for educational efforts and to encourage forward momentum: end 2015
- Map existing e-Health projects in cardiovascular disease and its prevention: mid-2016
- Organize a summit in 2016 to bring together consumer and patient organizations, health professionals and health organizations, public authorities, App developers, telecommunication service providers, and mobile device manufacturers with the ultimate objective to further develop the roadmap related to:
  - the development of evaluation standards/criteria for electronic tools
  - closer collaboration with innovative IT companies on existing ESC activities (such as Congresses) and the exploration of new activities
  - the development and dissemination of guidelines for the design of e-health trials, including appropriate endpoints
  - the development of guidelines on the proper conduct of e-health studies and implementation of e-health (code of ethics, standards, and professional involvement)
  - supporting appropriate reimbursement discussions and decisions, facilitating implementation of sustainable evidence-based e-health solutions

## Timeline

The ESC will review progress at least annually, and update the Roadmap (Table 2) as appropriate. The e-health agenda moves very rapidly, and it is important that the ESC is flexible enough to adapt to this changing agenda.

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## CARDIOVASCULAR FLASHLIGHT

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# Multi-modal imaging support in a staging percutaneous pulmonary valve implantation

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The patient is a 22-year-old female with a history of pulmonary atresia and ventricular septal defect. She was operated three times and during the last intervention the right ventricle-pulmonary artery conduit was changed because stenotic and was inserted a Shellhigh 23 mm. She developed significant pulmonary valve regurgitation and some degree of stenosis. The patient was scheduled for percutaneous pulmonary valve implantation that was done in two stages because of complex anatomy and long-time procedure. During the first procedure, two stents were implanted in the LPA and in the RV-PA conduit; the final results was a perfect landing zone for the following percutaneous valve and a severe pulmonary regurgitation (Panel A white arrows). In order to have as many information as we can, before and during the 2nd procedure a multi-modal imaging evaluation was done. She firstly underwent a CT scan (Panels B and C), and the information were used to create a 3D-printed model (Materialise's Heartprint, 3D-printed model-NV, Leuven, Belgium); this model allowed us both to better understand the anatomy and the complex relationship with the coronary arterial course (Panels D–F), and try to implant a valve before the procedure (Panels G and H). During the 2nd procedure, a 3D Rotational angio was obtained and 3D images were reconstructed in the interventional suite (using a 3DRA XtraVision workstation from Philips Healthcare, Best, The Netherlands). These images allows accuracy in evaluation of relationship between the right outflow anatomy and the coronary arterial course (Panels I and J). A 23 mm Sapien Valve (Edward Lifesciences, Irvine, CA, USA) was implanted without complications and with a successful final result, without valve regurgitation (Panel K).

