

Report of the ESC Digital Health Industry Forum

At the Sofitel Heathrow Airport Hotel, London, UK

8 January 2019

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INTRODUCTION

This report provides a summary of discussions at the ESC Digital Health Industry Forum which took place at the Sofitel Heathrow Airport Hotel in London, UK, on 8 January 2019.

BACKGROUND

Digital health isn't coming. It's already here. From e-prescribing to artificial intelligence, wearables and imaging analysis, digital health is rapidly gaining traction in cardiology and is set to become normal practice. Will cardiologists be replaced by robots? Where should the mountains of data being generated be stored, and who is legally responsible for acting upon it? Where is the proof that new technologies improve health or reduce cost? All of these questions and more were discussed during the forum by the ESC and industry partners.

FORMAT

The forum was hosted by the European Society of Cardiology (ESC) Digital Health Committee. Committee nucleus members opened the forum with the rationale for a core industry group working in partnership with the ESC on digital health (John Crawford), followed by the ESC's working objectives for digital health in cardiology (Martin Cowie).

Two keynote lectures were given by experts in cardiology and in digital health innovation, covering immersive health technologies in cardiology (Andrew Mitchell) and removing barriers and accelerating time to value (Guy Boersma and Des Holden).

Four interactive breakout sessions were held with ESC and industry representatives:

- How can the ESC provide value in: Educating cardiology healthcare professionals in integrating digital health in their practice?
- How can the ESC provide value in: Tool development for digital health cardiology?
- Should the ESC be active in: Advocating for digital health in cardiology – priorities?
- How can digital health provide value: For research advances and efficiencies?

Each breakout session was led by a moderator from the ESC Digital Health Committee who posed a number of pre-prepared questions. Feedback was reported to the entire group.

The forum closed with a summary of outcomes and future topics.

MAIN POINTS DISCUSSED

Introduction: Why an industry forum?

John Crawford, nucleus member of the ESC Digital Health Committee, spoke about the rationale for a core industry group working in partnership with the ESC on digital health.

The majority of participants attended ESC Congress 2018 in Munich and visited the Digital Health Area, which was overwhelmingly successful, indicating a high level of interest in digital health in cardiology.

The purpose of today's forum is to discuss the future of cardiology and cardiovascular healthcare, and how digital health might support it. Digital health refers to all the ways in which information technology can be used to support healthcare. That could be anything from smartphone applications to imaging systems to electronic health records to collaborative systems between doctors, and between doctors and patients.

Why is the ESC holding this meeting now? In April 2018 the Society set up the Digital Health Committee to focus on this emerging and fast growing area. The Committee aims to address the opportunities and challenges which the growth of digital health will bring, and to support the needs of ESC members.

The Committee wants to work with industry partners in a collective manner to make sure the ESC is doing the right thing for its membership and for industry. This forum provides a platform for existing and emerging companies involved in digital health in cardiology to shape the work programme, as well as events already planned for 2019 including a bigger Digital Health Area at ESC Congress in Paris plus a more targeted meeting later in the year.

The objectives of the Forum and the Committee are:

- Create a platform for strategic discussion with industry partners on digital health in cardiology and understand what is important to industry in this area.
- Discuss and prepare potential business applications of strategic priorities, including an in-depth event in 2019.
- Collect opinion from industry partners on issues that are considered market priorities and notable trends. What do you see happening, what is delaying the uptake of digital health, what could accelerate it better? Do we need more evidence, do we need more experience?
- Identify and prioritise further opportunities for collaboration with you as an industry grouping. (ESC Congress, education, innovation, advocacy, research, etc.)

ESC and digital health

Martin Cowie, Chair of the ESC Digital Health Committee, shared the ESC's objectives for digital health in cardiology. He emphasised that the ESC wants industry's feedback on the ESC's plans and where it thinks ESC efforts should be focused.

The ESC is one of the world's largest medical professional organisations, representing around over 109 000 cardiovascular health professionals in 57 countries. It is largely educational but also advocates, produces guidelines, and is increasingly involved in research and description of care patterns across those countries. ESC Congress is one of the largest, if not the largest, cardiology conferences in the world.

The ESC has become increasingly involved in the digital space. Prof. Cowie wondered if we would be using the term "digital" in 15 years' time, since it is actually normal practice. We are in an interesting period, moving from analogue to digital which is a generational, cohort effect, and technologies are evolving very rapidly.

To quote management consultant KPMG: "There is a new and rapidly changing healthcare landscape, where digital technologies are becoming increasingly normalised into the everyday delivery of healthcare."

This is a time of flux, making it a challenge for large organisations which have embedded practices from the past into their processes, but are not very clear about what the rules are for the future.

The UK's National Health Service (NHS) launched its long-term plan on 7 January 2019. This is a ten year plan, with Chapter 5 (Digitally enabled care will go mainstream across the NHS) recognising the need to scale up digital health innovation. It includes interoperability, remote monitoring, assisted decision making, artificial intelligence, and so on. But on the other hand, healthcare professionals say: "I've heard it all before. I work really hard, everybody keeps promising the earth, it's never delivered. We have to learn new systems but it doesn't seem to make a difference." Trying to bring together those two areas – innovation policy and the needs of professionals – is challenging.

Digital healthcare affects patients, who are at the centre of the digital healthcare landscape, and what they might be accessing. People use the term "democratisation" of data and of healthcare. It is patients' health, and maybe we need the expertise to be more accessible and convenient, with technology playing an increasing part in this.

The way professionals interact with patients and each other is changing rapidly across sectors. Cardiologists can share their expertise with anyone in the world, which is particularly important for imaging. This is potentially a paradigm shift and threatening to the current reimbursement models and income of cardiologists. In addition, digital healthcare changes the way organisations function.

Amidst all of these changes, how does the ESC decide which elements to get involved with, in terms of advocacy, education, and interaction with industry?

Referring to another quote from KPMG: “Digital technology has the potential to transform medicine and the healthcare industry in a sustainable way. At the same time, digital technology could equalise the relationship between medical professionals and patients.”

These statements look great on paper and the industry members here today have probably presented similar ones to your board, with statements such as “the potential to transform”, “disruptive”, “supportive”, “new paradigm”.

If you present that to an audience of healthcare professionals, you can guarantee they will start checking their emails. They do not buy into such grandiose statements.

Politically, in the European Union, there’s a belief that healthcare is slow to change, it is clunky, it’s not very enthusiastic about transformation, there are a lot of vested interests. The European Commission sees a huge potential for technology to change that model. It uses the key word sustainability, i.e. cost containment, which is a new model where the same number of healthcare staff can deal with an increasingly elderly, multimorbid population, using technology to get expertise to these individuals to deliver healthcare at home rather than in expensive hospitals with expensive specialists.

Already you can see the conflict between the policy level and the professional level. We have to be honest about these conflicts in the system and the different needs and perspectives of politicians and healthcare professionals.

What has the ESC done so far? An ESC position statement on e-health was published in *European Heart Journal* in 2016. (1) The paper outlined the ESC’s strategy for proactive involvement, for example through advocacy via its Brussels office, educating cardiovascular healthcare professionals, and engaging with companies and app developers at an early stage in the development process.

The ESC Board approved the set up of an ESC Digital Health Committee. The nucleus members are Martin Cowie (Chair), Enrico Caiani (Vice-Chair), Panos Vardas (Chief Strategy Officer; ESC President 2012 to 2014), John Crawford, Nico Bruining, Friedrich Koehler, Allan Bohm, Philippe Kolh, Martin Landray and Nicolas Duchateau. Every ESC association has a representative on the Committee.

The Committee’s main objectives are to define and implement a digital health roadmap, and assist with the coordination of digital activities of the ESC and its constituent bodies.

The Committee has a number of plans, which it is seeking industry feedback on:

Digital health portal

Digital health now has its own section on the ESC Website: www.escardio.org/digital-health. This will be a portal for all things digital for cardiologists, including ESC activities, video blogs, links to resources, etc.

A digital, multimedia format journal may be created. This would be the first such journal with a focus on cardiology.

Digital health track at ESC Congress

A bigger, even better Digital Health Area with a more prominent location is planned for ESC Congress 2019. This will be for all cardiologists, with cutting-edge innovations and research, examples of current practice, and industry booths featuring the hottest new technology.

ESC Digital Summit 2019

The first annual ESC Digital Summit will be held 5 and 6 October in Tallinn, Estonia, for digital health enthusiasts from Europe and beyond. Stakeholders include clinicians, key opinion leaders, digital technology developers and start-ups, and industry partners from the pharmaceutical and medical device sectors. This will be an opportunity to see cutting edge technology and contribute to discussions that will shape the future of cardiology.

#ESCdigital

A hashtag has been created to keep the conversation going on social media, in collaboration with the ESC's young community.

A survey of around 2,000 ESC members revealed that nearly 95% want to learn more about digital health and more than 75% thought digital would transform the way they work in the next ten years. There is a huge gap between what they know and what they want to know. Members were interested in conferences and online learning and in-house training as their preferred means of increasing their knowledge, particularly if they didn't know much about digital health.

Discussion about the ESC and digital health

One delegate said the plans show how the ESC will help healthcare professionals to upskill in digital. But what role does the ESC have in helping patients come to terms with using new technologies?

The ESC now has a cardiovascular patients forum. The perspective of citizens will also be incorporated via patient organisations. Cardiologists worry about a number of issues when patients present data they have recorded using an app. How accurate is the data, how can it be incorporated into doctors' own system, are they legally covered if they make decisions using that information? This creates a barrier between the patient using technology and the healthcare professional using that data to help advise them. These are the kinds of issues that the ESC aims to explore.

It was highlighted that pharmaceutical companies must deal with issues of privacy and compliance. Decisions in these areas depend on the European Commission, payers, and regulatory authorities, who are not fully active today when it comes to digital health.

The ESC has an Advocacy Committee and is very involved in the advocacy and regulatory arena. Enrico Caiani (Vice-Chair of the ESC Digital Health Committee) is a member of the EU e-Health Stakeholders Group. It is difficult to get reimbursement bodies to the table.

Today's meeting is the ESC's first step in broadening its discussion to industry. A future step will be engagement with patients, reimbursement bodies, and regulators.

The ESC's Brussels office, the European Heart Agency, was set up to empower advocacy. Activities include the [ESC Atlas of Cardiology](#) which maps inequalities and healthcare gaps in ESC member countries, the ESC cardiovascular patients forum, and work on regulation led by Prof. Alan Fraser.

The European Commission has been unable to get agreement from patients, clinicians, and industry on [m-health standards](#). Developers aim for new technologies to be functional, calibrated, and valid. But patients and healthcare professionals also expect technologies to improve outcomes.

Digital and e-health is a broad topic and delegates wanted to know if the ESC will focus on particular areas. For example research initiatives, ethics and compliance for partnerships, education, etc. That will shape how industry and others will partner with the ESC.

Education and advocacy are key pillars of the ESC. It also does some research. The ESC has no particular focus on electronic medical records or e-prescribing, as these cover all medical specialities. Areas of interest for the practice of cardiology include remote monitoring, artificial intelligence, image interpretation, apps, mobile health, and wearables.

Immersive health technologies in cardiology

Andrew Mitchell, Consultant Cardiologist at Jersey General Hospital and Honorary Consultant Cardiologist at Oxford University Hospitals delivered a keynote lecture on immersive health technologies in cardiology.

Problems facing modern healthcare

The volume of work is a principal problem, with the number of patients increasing rapidly. It's difficult to provide 24 hour staffing, and we need rapid access to investigations. Waiting times for echocardiograms, computerised tomography (CT), and ultrasound scans are getting longer. There is a delay and sometimes fear of implementing new technologies. Cost is also an issue – the UK for example spends around £191 billion each year on healthcare, growing at about 4% yearly, and amounting to approximately 10% of gross domestic product (GDP). Other European countries and the US spend even more.

There are increasing numbers of outpatients as cardiac patients now survive and acquire atrial fibrillation, heart failure, and cancer. The number of outpatient appointments in the UK doubled between 2006/07 and 2016/17. How will we deal with this problem? Will we keep bringing people in for a ten minute appointment? We need to start using more telemedicine, telecare, video consultations, Skype, and Babylon to reduce the number of people coming to hospitals. This should also help to reduce the number of non-attendances.

Immersive health technologies

Immersive health technologies can help us deal with the problems facing modern healthcare. These are devices that blur the line between the physical world and digital or

simulated world, thereby creating a sense of immersion. One type is *virtual reality*, a completely immersive experience in which users are taken from their real world surroundings and placed virtually into an entirely new digital environment using a headset and speakers. Another type is *augmented reality*, in which users can see the environment around them, but digital content is overlaid into their space – for example, Google Glass, Microsoft HoloLens, and the Pokémon GO mobile game.

There are enormous business opportunities in immersive health technologies, with the market share for healthcare due to double over the next couple of years. Alongside this there is an evolving and increasing healthtech market.

In 2018 immersive health technologies became clinically applicable with devices like the Oculus Go which has a built in PC. Devices could potentially be prescribed which would be cheaper than hospital appointments.

Virtual reality in cardiology

- *Physiological response*: Our work shows that virtual reality environments generate a physiological response. For example virtually walking on a plank looking down over a mile drop increases heart rate - people know it's not real but it feels real. Can we use that to assess heart rate variability, examine responses to medication, or perform a virtual stress echocardiogram without drugs or exercise?
- *Pain control*: We are starting to use virtual reality during pacemaker implants to reduce the need for analgesia or sedation.
- *Psychotherapeutics*: At least 30–40% of patients who have heart attacks, cardiac arrests, or device implants subsequently develop post-traumatic stress, anxiety or depression and virtual reality systems are being developed to help. Cardiac rehabilitation is another promising area. We are using it this year to control heart rate during CT coronary angiograms and provide better quality images.

Virtual reality examples from around the world

- *Stanford Virtual Heart Project*: The Lucile Packard Children's Hospital Stanford developed a standalone virtual reality anatomy package to explain complex congenital heart defects. Children, parents, doctors and surgeons can look in detail at an individual's heart. It helps children understand their surgery.
- *Cardiac rehabilitation*: Work has been ongoing for about ten years. Exercise with a virtual reality component improves exercise duration, reduces sympathetic tone, and promotes recovery after interventions.
- *Simulation training*: Virtual reality environments can be used to assess trainees' response to scenarios, such as cardiac arrest. Physiological responses including heart rate, respiration, and skin sweat responses can be measured. Trainees are given feedback so they are better able to function in stressful scenarios. There is the possibility of using this for continuing professional development (CPD).

Potential uses of augmented reality

- Teaching / training.
- Medical simulation training.
- Virtual consultations: patients could wear a headset at home.

- Emergency care: specialists on call could put on a headset, creating an avatar in the emergency room where they can provide advice.

Examples of augmented reality in practice

- Medical students at the Cleveland Clinic are using the Microsoft HoloLens to perform holographic dissections.
- Echopixel uses standard CT or DICOM datasets. Users wear glasses to visualise cardiovascular anatomy and manipulate it with a pen.
- CAE has developed a system to simulate and teach transoesophageal echocardiography using the HoloLens and a probe.

Improving access to investigations

How can digital health technology be used to improve access to investigations, reduce waiting times, and minimise specialists' time? CT coronary angiography, for example, is the standard way to diagnose coronary heart disease and it is estimated that the number of procedures should triple to meet demand. But access is limited with insufficient cardiologists and radiologists.

Examples in this area include the fat attenuation index (FAI) developed by Caristo to measure perivascular inflammation. The FAI is a strong predictor of cardiovascular risk and could help clinicians give medications to patients who will benefit most. Images are analysed remotely without the need for onsite analysis.

HeartFlow uses a standard CT dataset and computational flow dynamics to non-invasively assess whether artery narrowing is functionally significant. The company calculates fractional flow reserve which can then be used by onsite clinicians to plan the number of stents needed and how long it will take.

Dealing with data

There is a vast increase in wearables and connected devices and we are collecting an enormous amount of data. With the new internet of things 5G networks coming through this will get even better. What should be done with the data? And is it having any benefit?

Where will data be stored? The patient should be the data controller, not institutions and companies. Perhaps what is needed is a patient-controlled record system. Patients need to take their data with them and should be able to choose who looks at it, rather than clinicians making that choice. Patient control of data access makes it easier for companies to plug in because they can ask patients directly – for example to try out a new diabetes testing device.

Digital Jersey

Jersey is trying out a system where the patient holds their own Jersey Care Record. All of the data silos feed into that including the GP, hospital, pharmacy, family/friends, digital developers, etc. Patients can choose if they want to share their data.

Clinical validation of technologies

How do we prove that the data that has been collected will make people feel better or live longer, or reduce cost? We need rapid access to quality assured, outcome measured clinical research. But how and where should that research be performed?

Small communities that are less geographically mobile make it feasible to collect longitudinal data. In these communities there is good collaboration between primary and secondary care, a smaller number of health record systems, and independent health regulators. Doctors, nurses, and the public become engaged with the research, enabling healthier populations and potentially stimulating new economies.

People have discussed the “walled garden” as a place to do research. Dr Mitchell proposed the “shored garden” or the island as a platform.

The local government in Jersey is supporting an initiative to promote the Channel Island as a leader in digital health testing and innovation. Jersey has a population of 102,700 and GDP of £4.11 billion. It is easy to get to. The government has invested in digital connectivity meaning that every house has a fibre cable and there are two 4G networks, making Jersey the most digitally connected place on the planet. There is an active tech community, a stable and independent government, strong public finances and a competitive tax base.

One of the early projects invited residents, via a newspaper advertisement, for a free heart test at the hospital using the AliveCor heart monitor. Nearly 1,000 people were screened over three days, making it the largest study of a handheld ECG.

This has expanded so that residents now receive a timeslot, then rotate through up to ten workstations and try out different digital health technologies. To take two examples, B-Secur has developed the HeartKey which uses ECG biometrics for health and security, and Cardiocity is developing a way to measure blood pressure from the fingertips.

The Jersey immersive health laboratory, called Immersion, launches later this month and will conduct research on virtual reality and augmented reality. One project is virtual reality stress testing.

Jersey Heart for Life is looking at population screening for heart disease. Residents will undergo DNA mapping, which will be linked to the Jersey Care Record.

Conclusions

The rapid evolution of digital health technologies has created one of the most exciting times in history to be in the field of medicine. Immersive health technologies might solve some of the current problems in healthcare by bringing consultations to the patient’s home and specialists to the emergency room. Patient centred records are vital to the way we will work in the future, with patients as the data controller and eliminating silos. Patient-driven data from wearables and the genomic revolution will enable us to provide personalised, precision medicine.

Discussion on immersive health technologies in cardiology

The question was asked whether physicians should also be mathematicians. The reply was that most cardiologists are mathematicians, solving equations every day. We don't need to get bogged down in the statistics but fundamentally we are problem solvers.

How many years will it be before big data and digital health change our practice? Artificial intelligence is already here. Some technologies are already better than humans, for example Google DeepMind software is at least as good at analysing retinal images as the top doctors from Moorfields Eye Hospital.

Are non-human physicians coming? Humans are computers too. Good cardiologists have treated thousands of patients. Computerised systems can be exposed to even more patients, and therefore be even better. As physicians we don't need to be scared about artificial intelligence because we can use it to augment our care – the computer says “I think that's melanoma” and the physician can decide if they agree. Babylon's chatbot is one example.

Venture capitalists now speak about “supportive” rather than “disruptive” technologies. People are not always receptive to change and transformation, so “human plus artificial together get the best results” is a good way to sell artificial intelligence to the medical community.

Should ESC meetings show the use of virtual reality and augmented reality to educate about cardiac anatomy and electrophysiology procedures and to conduct consultations with patients? Should we have demonstration zones or is that a step too far?

Once you put a headset on it changes everything. You can't imagine it through pictures. But if the ESC is going to promote technologies it has to be sure they improve healthcare outcomes.

A number of delegates spoke about their work in virtual and augmented reality and said a demonstration zone would be possible. There was a request for a live stress test using virtual reality at ESC Congress as this would help clinicians see its use in clinical practice. Most people think of virtual reality as purely for education.

Creating excitement about virtual reality has been relatively easy, but getting technologies financed for systematic use is very difficult. There are fixed payments to treat heart failure, for example. The sooner we get payers on board, the quicker we can move from excitement to reality.

Economics and reimbursement will be one of the main topics at the ESC Digital Summit 2019. Few countries reimburse telemonitoring of cardiac devices. If healthcare systems can be persuaded to start paying for useful technologies, start-up companies should be able to attract more investment.

Google, Amazon, and Apple are three big players, with the latter developing a patient centred records system for the iPhone. They will probably buy up companies and incorporate their technology. We shouldn't fear that, as new possibilities are opened up.

How can the ESC provide value in: Educating cardiology healthcare professionals in integrating digital health in their practice?

Breakout session moderator: Allan Bohm

Widespread adoption of innovative technologies is crucial for the survival of companies but that needs to be preceded by education. How can education address knowledge gaps, fears and barriers to adoption, without just being about buzzwords and gimmicks? A flexible, mixed approach is needed with various options to meet the needs of different audiences and show how digital health can provide value for them.

What knowledge gaps, fears, and barriers do healthcare professions have in digital health?

Lack of evidence based medicine

Trust is key, and a lack of evidence prevents faster development and adoption of new technologies. Clinicians fear that technology won't do what is claimed by suppliers and want published research for validation.

Data integration

Even if there is good evidence for a technology, and doctors trust and respect the data it generates, GPs and hospitals need to integrate that data into their own systems. Clinicians worry about making mistakes if they manually input the data. Even with the increasing adoption of health informatics standards such as HL7 and FHIR, start-ups may be unable to create an interface into other systems, creating a barrier to adoption.

Litigation

Validation of technology is linked with the legal implications of malpractice/mistakes. Doctors need to trust a technology before they can base clinical decisions on the data it generates.

Reimbursement

Failure by health authorities to reimburse new technologies is a barrier for practitioners. For those in private practice, a driver of adoption will be enabling doctors to expand their business either through financial reimbursement or non-financial added value.

Fear of being replaced by robots

Some doctors fear being replaced by robots, artificial intelligence, and apps. Patients now arrive at consultations with more information than the doctor has, which may be intimidating. Physicians want to make the treatment decisions and not have it dictated by an algorithm the patient brings in. We need to move from disruptive to supportive, showing physicians how technology can help them treat patients.

How should the ESC assess knowledge gaps and deliver education in this area?

Surveys and social media can be used to ask healthcare professionals what areas of digital health they want to know more about. But “people don’t know what they don’t know”, so the ESC’s role is also to identify gaps that clinicians are not even aware of.

Regarding delivery of education, the solution is a jigsaw of different offerings. Clinicians may only need two or three pieces to be convinced, others may need the whole puzzle. Young cardiologists will turn up for a show and tell of exciting new technologies but are not in a position to persuade hospitals to adopt a new approach or pathway. Senior cardiologists have the authority to influence change, but are less interested in new technologies and see the hassles around integration, regulation, and reimbursement.

Frameworks and patient pathways

The ESC could develop a framework of new patient pathway options, showing how new digital tools can be incorporated. This approach uses clinicians’ language, and may be more effective with senior cardiologists than talking about products.

Best practice examples

The ESC could develop case studies of successful implementation of digital technologies, with published research showing good outcomes and how the clinician navigated the legal and regulatory aspects.

List of approved technologies

A list of ESC approved technologies would be another form of validation and boost clinician confidence. This could take the form of a TripAdvisor type rating site, in which clinicians and patients give products a score. App developers already use the net promoter score. ESC conferences could then have sessions built around the year’s top ten apps, which would show app developers what cardiologists do and don’t like.

Basic and advanced training

Young doctors are interested in digital health but education is currently poor or nonexistent. There was a consensus that digital health should be integrated as a full chapter in the ESC Core Curriculum. CPD points could be awarded for digital health training.

Barts Medical School has set up the first digital health programme for medical students, called Barts X Medicine, which could be a model for the ESC. Students undergo a week of immersive teaching, and then develop a digital solution.

The ESC should offer basic and advanced training opportunities at its events. Basic education aims to increase awareness – for example visionary speakers, who attract large audiences but do not generate adoption of technology. This can be beneficial for some companies who need people talking about their product.

More advanced training could be a best practice example from a clinician on how he/she implemented a technology and the pathway used. The session will attract a smaller

audience but generate more customers – good for businesses at the stage of needing early adopters and champions.

How can the ESC provide value in: Tool development for digital health cardiology?

Breakout session moderator: John Crawford

This session focused on what the ESC's role should be in digital tool development. Should the ESC set up quality indicators, standards, and certification for product development? Is a collaborative platform needed to link investors and researchers? Should the ESC take an active role in creating tools for the cardiovascular community, perhaps through consortia?

There was a consensus that the ESC's real value is as a connector, convener, and enabler of stakeholders rather than developing products or investing in tools. The ESC needs to capitalise on its existing assets – for example guidelines and registries, which are well established and have authority, and also the new patient engagement group.

Digital health community

The ESC should identify a large group of ambassadors and early adopters. It could take the form of an ESC Digital Health Community (similar to the ESC Young Community). Members of the group could be identified by awarding points for attendance at digital health sessions during ESC Congress.

The ESC could then connect these cardiologists with industry, so they can try new tools, validate them, and diffuse them out into the wider cardiology community. Focus groups could be held with one company and a selection of cardiologists who could help refine that company's tools.

One idea would be to identify the two or three biggest challenges facing cardiology today that have validated solutions. The ESC could help accelerate adoption of those solutions using its digital health community.

Patient database

Clinical trials and gaining access to real patient data is too expensive for many developers. The ESC could use its existing registry data to create an anonymised patient database with information on imaging, drugs, outcomes, etc. Companies could use the database to test and validate their digital tools and algorithms. This database could become a benchmark to help companies meet regulatory requirements and speed up the release process.

Patient engagement group

The ESC could bring together its patient engagement group and industry partners, for example using workshops to discuss specific questions from industry. Focus groups could be held for a company in the final stages of tool development to test it informally with patients.

Standards and interoperability

The ESC is not a standards body but should advocate for a globally accepted validation method which could then be endorsed by the ESC. The proposed ESC patient database could become the standard, clinically relevant, test database for regulatory approval. Awareness

around certification is needed so that cardiologists understand which medical and wellness technologies have achieved agreed standards and can be trusted.

The ESC needs to champion the need for interoperability and efficiencies of scale. Interoperability with existing systems will facilitate adoption, is a major factor in promoting growth, and is needed for digital transformation. The ESC could put pressure on governmental bodies to enforce interoperability. In Belgium, for example, devices are only reimbursed if they are interoperable with hospital systems.

Digital transformation plan for cardiologists

The ESC could create a digital transformation plan for cardiologists in practice. This type of guidance is needed because even when validated tools exist, many cardiology departments don't know how to integrate them into their daily work. The ESC could establish a roadmap and guidelines on how to run a digital transformation project within a cardiology unit.

The plan could be a Call to Action, outlining why adoption of digital health is essential for sustainable healthcare and how failing to do so will leave them struggling to cope with current challenges. The problem of low adoption is not just generational, but requires a new mindset and a culture change. Cardiologists need to believe that this is important.

Priorities and scope

The ESC needs to focus its scope and priorities. What are two or three crucial areas that are both important to cardiologists today and can be solved in the relatively short term by applying the right technologies? Taking this approach will make it possible for the ESC to achieve its goals, while a very broad approach will fail to achieve anything of note.

Advocacy: Removing barriers and accelerating time to value

Guy Boersma (Chief Executive) and Des Holden (Medical Director) of the Kent Surrey Sussex Academic Health Science Network (AHSN) gave a keynote lecture on how to remove barriers and accelerate time to value.

The 15 AHSNs in England were established to spread innovation, improve health, and generate economic growth. They do this by connecting organisations in the public and voluntary sectors with industry, and creating the right environment for industries to work with the health and social care system.

Advocating for system change

Mr Boersma's role centres on advocating for system change to enable successful projects to be implemented.

There are blockages at each step of the innovation pathway:

- Research and development (R&D): *"persistent nature of the gap between health R&D needs and the R&D that is presently funded and undertaken"* (Rottingen et al 2013)
- Spread and adoption: *"Of more than 25,000 reports published in six leading basic science journals between 1979 and 1983, 101 included confident claims that the new discoveries had clear clinical potential, yet only five had resulted in interventions with*

licensed clinical use by 2003, and only one led to the development of an intervention used widely” (Chalmers et al 2014)

- Capacity to deliver: *“Our problems with innovation are probably a product of the disconnected and disengaged research system producing innovations that the healthcare system has neither capacity nor will to implement” (Walshe 2015).*

Sustainability and transformation gets little attention compared to “getting by” operationally. But we are now in an era in which hospital chief executives view success as including some elements of transformation – doing work now that will make services sustainable in the future.

Health systems research is a small field, making up just 7.5% of UK health R&D. But spread and adoption receives even less UK investment than R&D. The reverse is true for private sector partners in the UK healthcare system, who spend more on spread and adoption than on R&D.

The collective budget of the 15 AHSNs, whose focus is spread and adoption, is £50 million, and they are advocating for that to increase so that the results of R&D can be capitalised on.

Accelerating change

AHSNs work across the innovation pathway, but central government funders and local members are keenest for them to focus on supporting the faster adoption of well evidenced, beneficial service changes or technological innovations that work well somewhere in the world.

They do this by:

- Building partnerships between all organisations involved in healthcare: NHS, academia, social care, third sector, and industry.
- Identifying and responding to common priorities.
- Building capacity and providing expertise on areas such as patient safety, informatics and evaluation.
- Importing what works best from other areas.
- Building the national reputation of NHS organisations.

Advocating for “boots on the ground”

The spread of innovation requires dedicated people – “boots on the ground”. Vocal, committed champions for change who have credibility among their peers are needed. Project managers must have enough time in their job to support change.

Advocating for value for money

The NHS in England focuses on balancing the books and delivering promises within the financial year, and too little attention is paid to multiyear programmes. Value for money should be the focus, rather than cost, which can include spending now for future benefits.

Advocating for pooled budgets

The NHS has separate budgets for hospitals, GPs, mental health services, and so on. Innovative projects on prevention and early intervention would benefit from pooling budgets. This may lead to savings in some parts of the system but not others.

Advocating for innovative environments

Innovation is too often viewed as a luxury. Clinicians lack the time to prioritise innovation or identify problems, and there is a lack of incentives in the system to make time. Change and innovation requires a receptive environment, and capacity for delivery.

Living longer but not better

People are living longer but with an increased burden of illness. Clinicians currently think in terms of sequential intervention. Patient presents with an illness, we take a history, we diagnose, start with a therapy and possibly discuss lifestyle modification. We monitor the condition intermittently and make sequential interventions on the basis of relatively small amounts of information.

Technology – the flow and analysis of information – will enable clinicians to deliver better care. That means using data to prevent illness and increase life expectancy with minor, rather than severe, impairment.

The flow and language of information

Using data requires improving how it is recorded and joined up. England has some exemplars where information flows with the patient, and primary, secondary, and tertiary care can see and add to the record. But this is rare.

There is no unified way of describing the information that is entered into a dataset so that it is relatively clean for interrogation by algorithms. Information that could help predict cardiovascular risk is recorded in different ways. We need to focus on agreeing a language for that information that allows comparison and machine learning.

Kent, Surrey, and Sussex has two good datasets. The East Kent dataset takes information from primary, secondary and social care and integrates it into a single care record. The Clinical Practice Research Database national dataset holds 11 million primary care records for existing registered patients, all of which are updated on a fortnightly basis. It is useful for investigating outcomes in relation to recorded information.

Ask the public

The public already thinks that healthcare professionals have access to the same information, and complain when they are asked the same questions in different settings. They expect this level of sharing. The debate is likely to be whether we should go a step further and add over-the-counter purchases to the record, alerting us to screen for ailments.

Members of the public prefer to articulate a problem and then hear what solutions could meet that need. They are less willing to engage when they are presented with a solution and asked if it addresses any of their problems.

Case study: Patient Knows Best

A platform was established at Surrey and Sussex Healthcare NHS Trust whereby 900 patients with inflammatory bowel disease can view their own notes and diagnostics, including blood results, imaging, and histology. It enables them to self manage, modifying their drugs based on blood results and how they feel. There is evidence that flare-ups have reduced because patients can phone for advice at the first sign of trouble rather than waiting for an appointment. Satisfaction rates are high, and increase the longer patients use the system.

The Royal College of Physicians has included this example in its model of sustainable care. There are plans to spread its adoption to other centres and other chronic diseases.

The AHSN's top three priorities

Mr Boersma concluded the lecture with the AHSN's top three priorities. First, encouraging the system to take a more holistic approach to patient's care and experience. Second, overcoming budget silos and fragmentation in the system by linking physical and mental health, primary and secondary care, and health and social care. And third, putting a greater focus on value for money and investing now for future generations.

Should the ESC be active in: Advocating for digital health in cardiology - priorities?

Breakout session moderator: John Crawford

What should ESC advocacy priorities be in digital health – key audiences and messages?

A good start point for advocacy in digital health would be to classify technologies into who uses and pays for them. That will determine the messages we want communicate. For instance, health apps are used by patients, data management systems are used by hospitals, and pacemakers are used by implanters.

Targeting decision makers is key. Companies often show value to the user, who then has to convince the payer. The messages of value to these two groups will be different.

The ESC can use its existing relationships with politicians in Brussels, journalists, patients through its new group, key opinion leaders/lobbyists, regulators, insurance companies, healthcare systems/decision makers, and industry (pharmaceutical, biomedical technology, and digital health).

A timeframe for advocacy should be defined, as that will determine how messages are pitched to the various stakeholders. Are we discussing value in two years or ten years? For example, digital health could improve diagnosis of arrhythmias and cardiovascular imaging over the next ten years, but is that too long a timescale?

Payers

Payers and insurance companies are a crucial, and potentially the main, audience for advocacy. These organisations have the power to authorise spending on innovations in the healthcare system. Showing them that digital health saves money will turn them into advocates for adoption.

The ability to demonstrate value to payers depends on the technology. It may be difficult to show the real value of a mobile app which supports patients after a heart attack, but easier to show how a machine learning tool could replace manual interpretation of diagnostic images in a patient pathway, for example.

Patients

Patients purchase digital health products, and can put pressure on providers of healthcare services to offer products. In the area of medication compliance, for example, we know that 50% of patients stop taking their drugs. If they use a digital tool to measure their blood pressure and see that drugs keep it under control, they may feel more confident to take their pills even when they feel well. They will then ask their physician for the monitoring system because they are convinced it will improve their health.

National innovation units

Each European country has an innovation unit, often set up by the government and responsible for making digital health a reality. Organisations like the AHSNs in England can have a great deal of reach and influence. Their job is to look at new ideas and promote effective ones. They may conduct their own research on a product, providing independent validation, then recommend it to national payers and even help negotiate a price. Innovation units have an inherent interest in digital health being successful because their mission is to achieve widespread adoption of high impact innovations that improve care and/or reduce costs, and to create new jobs and economic value in their regions.

Is there enough literature on the economic impact of digital health? What should be studied first?

European healthcare systems try to balance cost, quality and access. There is insufficient data to demonstrate that digital health reduces cost while maintaining quality and increasing access. Effective advocacy requires being able to show that implementing an innovation will make a positive difference to a healthcare system.

ESC Atlas data could be used to identify costly areas in cardiology which have digital health solutions – for example undiagnosed heart failure, atrial fibrillation, and cardiac rehabilitation. Focusing on cases providing value today would enable the creation of a compelling offer to healthcare systems and hospitals showing how digital tools can help with prevention and adherence to treatment. Cardiac rehabilitation suffers from non-attendance and insufficient provision – remote systems and behaviour change apps could improve uptake and outcomes, and save costs.

For example, Atlas data has already revealed that many ESC countries don't have enough implantable cardioverter defibrillators (ICDs) for secondary prevention. This provides an opportunity to advocate for authorities at state level to meet this need.

Should the ESC advocate in partnership with other reference groups in the field and which ones? Which topics should be addressed first?

Medical specialties

The ESC should advocate with other medical specialties grappling with the same concerns, including interoperability, legal issues, data privacy. Many of the arguments will be similar, so it would help societies and associations – for example in oncology, diabetology, and neurology – to pool thinking and resources. The ESC could take the lead in such an alliance, targeting politicians and hospital directors. Diseases and digital systems span hospital departments so it makes sense to collaborate.

Technology bodies

Technology bodies could be valuable partners for the ESC. For example COCIR, the European trade association representing the medical imaging, radiotherapy, health ICT and electromedical industries. COCIR is an important European entity for promoting e-health.

The ESC is already in discussions with the Healthcare Information and Management Systems Society (HIMSS), a US not-for-profit organisation. HIMSS holds the largest healthcare IT conference in the world, attracting around 45,000 technologists, managers and buyers. HIMSS wants to connect more with doctors and generate discussions around delivering services and how to involve patients. There is an opportunity for HIMSS and the ESC to get involved in each other's events.

Committee of national cardiac societies

The ESC should set up a core team on innovation/digital health with one representative from each national cardiac society. They may have ideas we are not tapping into, and could be the first ports of call for advocating with local organisations and governments.

Discussions in this group would reveal best practice and enable the ESC to set a standard. Members who have implemented a digital tool can share how they negotiated reimbursement with the local ministry. Less advanced countries would have access to advice on how to successfully adopt innovations.

How can digital health provide value: For research advances and efficiencies?

Breakout session moderator: Martin Cowie

This session explored how digital health can be validated through research. Participants were asked what the ESC's role should be in the research arena. Should it get involved in cutting edge research programmes using digital health innovations or run collaborative registries involving digital tools?

Changing the mindset of cardiologists

The ESC is the medical authority that can change the mindset of cardiologists towards embracing digital tools and new research models. It needs to be seen as a driver of innovation. Most cardiologists are relatively passive about digital health and don't see themselves as having a role in digital transformation. But they will adopt digital technologies that help them do their job efficiently, safely and effectively.

The ESC could outline a roadmap of what the cardiology profession will look like in three to five years, including threats to the profession and major challenges, such as the ageing

population and a rise in outpatient appointments. And then how should cardiologists use digital health to keep pace with the change that's coming. Show them the options so that they can choose digital tools that will help them in their practice.

A Cardiovascular Round Table for digital health

The ESC should be a facilitator of innovation in cardiovascular medicine. ESC and industry representatives could convene in a Cardiovascular Round Table (CRT) for digital health. The idea being to understand the objectives of all stakeholders and produce a framework that cuts across advocacy, education, guidelines, research, etc.

The current CRT model is to hold a workshop, which is followed by a manuscript. For digital health this could outline the key issues, what the ESC views as good practice, and what it is looking for in innovative products.

It was highlighted that there is a difference between validating a technology, i.e. showing it works, and validating its implementation, [which must demonstrate clinical and economic benefit](#). The majority of costs and research are put into the latter, which is the end goal for receiving reimbursement. The clinical community expects technical validation as a starting point. For them, real validation is when research shows that using a technology improves patient outcomes and is safe.

This forum would allow companies to explain why their research methods make sense for their product. The ESC could help bring groundbreaking technologies into the limelight and maximise their benefits as quickly as possible. On the other hand, the ESC could tell companies when more evidence is needed before the ESC will give its stamp of approval.

Evidence requirements for ESC guidelines

ESC clinical practice guidelines can drive adoption of a newly licensed digital product. Participants asked for clarity from the ESC Digital Health Committee for Practice Guidelines on what evidence base it requires for different types of digital technologies and how that is graded. Companies would then know the type of data and evidence they need to produce for their product to be recommended by the ESC.

Regulators like the European Medicines Agency value the views of professional bodies like the ESC. If the ESC said, for example, that randomised controlled trials (RCTs) are the only form of acceptable evidence and registry based studies like SWEDEHEART are insufficient, regulators may be influenced to take the same view. On the other hand, if the ESC said non-RCT models of evaluation were acceptable for digital tools, the regulators might follow suit.

New models to evaluate digital technologies

RCTs are the gold standard for evaluating medicines but not only are they expensive, they may not be fully applicable to digital technologies. The added value of remote monitoring and other digital applications can be difficult to demonstrate in an RCT, and real effects seen in individual patients become undetectable.

There is an urgent need for discussion on new, reproducible models to robustly evaluate digital technologies. The ESC could outline a structure of the evidence needed for different types of digital technologies.

The value of patient generated data should be clarified, as well as its role in the validation of digital technologies. Currently companies have difficulty publishing studies based on such data and they believe its scientific value is underestimated. They want guidance on how data generated by digital technologies is perceived from a scientific perspective. What is its value for publishers and guideline writers?

The availability and scalability of big data have made observational studies more prominent. How can the complementary information from big data be used to provide the missing parts of the puzzle not provided by RCTs?

As alluded to above, there was a view that the ESC should advocate for new models of digital technology evaluation, or health technology assessments, to be accepted as valid evidence by regulators and health technology assessment bodies.

The ESC's role in research

There was no clear view from participants on whether the ESC should be conducting and facilitating trials and registries that use digital technologies.

Showcase innovations

The ESC should use its lighthouse function to shine the light on companies, cardiologists, and researchers using digital innovations.

Clinical trials which the ESC thinks demonstrate sufficient evidence for a product should be showcased. That data should be shared across the ESC community with perspectives from key opinion leaders in Europe on the impact it could have on their country or their practice. This would show all cardiologists, not just the early adopters, how digital technologies will affect their practice in the near and more distant future.

ESC Congress could have a session on late breaking digital technologies. These would have to be separate from the traditional late breaking trials, which are judged on the basis of study size, number of centres, and evaluation of hard outcomes. Unless a new criterion was introduced: the impact on clinical practice in the next 5–10 years. All late breaking trial submissions could then be judged by the same standards. To take one example, telemedicine is likely to have a greater impact on practice in five years than any drug.

Digital awards were given at ESC Congress, and it was suggested that this would be a good way to recognise the leadership and innovation of companies, cardiologists, and researchers. Awards for services to the future of cardiology could acknowledge companies that have forged a path ahead and cardiologists who have trialled a product or implemented a digital transformation plan in their hospital.

Summary of forum outcomes and future topics

Participants discussed digital cardiology in the round and considered whether the ESC needs more focus on standards, interoperability, tools, advocacy, education, and research.

One participant asked whether the ESC itself could become more digital by offering virtual meetings, for example. The ESC already hosts webinars. Industry partners are keen to support upcoming digital initiatives. Regarding the initiatives already supported by industry, is there scope to expand the reach and impact using digital channels? For instance could a sponsored workshop be put online and distributed through various digital platforms?

The ESC is set to publish a paper on social media and cardiology. It wants to work in a blogosphere territory to increase its reach globally, particularly to young cardiologists and cardiologists who can't attend ESC Congress.

Participants asked for the opportunity to suggest sessions and speakers for the programme of ESC Congress in Paris and the Tallinn meeting. They also wanted to be notified of new publications and activities in digital cardiology.

The ESC plans to hold future industry forums and will investigate how the group can stay connected on a more continuous basis. For example some type of online platform for the ESC to share information, updates and plans with the group. A conference call was suggested after the next Digital Health Committee meeting in March to distribute the document from the Digital Health Industry Forum and present an outline of the programmes at ESC Congress and the Tallinn event for feedback.

The question was posed whether the ESC Digital Health Committee would include industry representatives. The Committee has representatives from the guidelines committee and all ESC associations, plus the nucleus. Discussions with industry will be through the Digital Health Industry Forum.

A suggestion for next forum, and the Tallinn meeting, was to stream some sessions by theme (pharma and therapeutic compliance, imaging, big data, devices, etc) to allow for more focused discussion on advocacy and other topics. Future forums might incorporate other components of the ESC into the meeting – for example patients and advocacy.

John Crawford and Martin Cowie thanked everyone for attending.

NEXT STEPS

- Report of today's forum for ESC management and membership.
- Conference call with industry partners following ESC Digital Health Committee meeting in March.
- Bigger Digital Health Area at ESC Congress 2019 in Paris, France.
- ESC Digital Summit 2019, 5 and 6 October in Tallinn, Estonia.
- Future Digital Health Industry Forums to be confirmed.
- Platform to be established for updating the group on ESC plans and new information.

NOTES

Participants

- **ESC Digital Health Committee nucleus members:** Martin Cowie (Chair), Allan Bohm, John Crawford, Panos Vardas.
- **Keynote speakers:** Guy Boersma, Des Holden, Andrew Mitchell.
- **ESC staff:** Aoife Delmas, Turo Laitinen, Malek Lebsir, Nata Nambatingué.
- **Industry partners:** AliveCor, Amgen, Bayer, Boston Scientific, Cardiomatics, Feops, FibriCheck, GE Healthcare, Johnson & Johnson, Medopad, MSD, Novartis Pharma, Pfizer, Siemens Healthcare, WeHealth by Servier.

References

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About the European Society of Cardiology

The European Society of Cardiology brings together health care professionals from more than 150 countries, working to advance cardiovascular medicine and help people lead longer, healthier lives.