## CARDIOLOGY MANAGEMENT

Volume 4 - Issue 1, 2010

NEW HORIZONS FOR CARDIOLOGY

#### **FEATURES**

Diastolic Dysfunction and Diastolic Heart Failure

#### **INTERVENTION**

Developments in Structural Heart Disease Interventions

#### **MANAGEMENT**

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#### Editorial

#### Shrinking the Gaps: E-health and Cardiology

According to Moore's law (named after Intel cofounder Gordon E. Moore), computer capacity increases exponentially, approximately doubling every two years. Two decades ago, for many medical professionals, a computer was still a novelty. Nowadays, an office without one looks bare, incomplete.

The healthcare industry has been slow to adopt this new technology. Understandably, caution has been the watchword. Rather than being welcomed and embraced by cardiologists, computers initially penetrated our ranks by stealth, disguised as echocardiographs, digital ECG recorders, or implantable devices.

Until quite recently, the use of computers in medicine, now called e-health, was at roughly the same stage as the motor car industry was a century ago. Technology is now progressing much faster than it was then, but the three factors that transformed the car from an expensive toy for the hobbyist into the everyday necessity we take for granted also apply to computers: accessibility, standardisation, and cost. Now, as e-health attracts ever-growing interest, we should keep these three factors in mind as we scrutinise the burgeoning array of options on offer.

Historically, the practice of medicine has been hampered by distance: the distance between patient and physician, between general practitioner and specialist, between specialist and the patient's medical records. Never before have those gaps, in both distance and time, been smaller than they are today; and the gaps are still shrinking. Twenty years ago, mobile phones were rare, most people had not heard of the internet, and the World Wide Web had not yet come into existence. Nowadays, it is almost taken for granted that any e-health system should have a network dimension as a major component.

Telemedicine is a particularly promising domain for cardiology, because we know that early interventions can be extremely cost-effective, as well as beneficial to the patient in terms of survival and recovery. Teleconsultation can shrink the gap between a patient (or GP) and the consultant cardiologist at a regional hospital. Home monitoring for patients with chronic cardiac conditions, especially the elderly, can save them unnecessary trips to hospital, while giving them continual reassurance about their status. Future developments in wearable devices are likely to extend this kind of application even further.

The electronic health record has been around in one form or another for a long time, but the expansion of computer networks, local, regional and worldwide, has transformed the possibilities. Most of the security questions have already been answered in order to meet the exigencies of international finance, and the door is now open for the free (and secure) exchange of medical information to allow collaboration within and between healthcare centres. And why should motivated citizens not have access to their e-health records, just as they already do to their e-banking records?

Medical databases can also find application outside daily practice, providing valuable core data for clinical trials. Some see the integration of medical record systems and clinical trial databases as one of the main challenges for medical informatics. Here, of course, interoperability is the key. Although it is not easy to replace natural language by codification schemes such as ICD and SNOMED without losing important information, the standardisation of terminology and coding is a prerequisite for information sharing on a broader scale.

And of course, we must count the cost. Investments in e-health must undergo the same rigorous cost-effectiveness analysis as developments in other areas of medicine, before the respective technology can be incorporated into guidelines. e-health should be considered first and foremost as an investment in better healthcare.

There is not the space here to discuss more ambitious projects, like the Virtual Physiological Human, in silico environments, personal health systems, or tailored drugs. These applications must await the future; others are already with us. However, here, too, the gap is shrinking, and it is likely that, within the professional lives of most people reading this, the practice of e-cardiology will take us to places we can barely imagine.

Yours faithfully,

Panos E. Vardas, MD, PhD Professor of Cardiology



Editor-in-Chief Professor Panos E. Vardas



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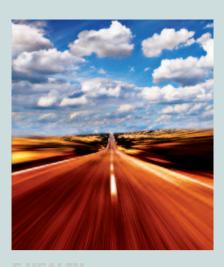
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Co-Founder of the European Society of Cardiac Radiology Talks About Collaboration Between Cardiologists and Radiologists



#### NEW HORIZONS FOR CARDIOLOGY

Telecardiology is one of the fastest-growing fields in telemedicine. Already, a significant quantity of published clinical data, with some randomised multi-centre trials, demonstrate that its potential future applications are many, and that health-care can benefit in a multitude of different ways. In this cover story we attempt to cover some of the most important of these applications: the use of electronic health data in research and clinical trials, its potential for more cost-effective remote monitoring, and its applications for vulnerable groups such as in paediatric telecardiology. Finally, we publish a guide for making e-health investments for healthcare managers.



#### CARDIOLOGY LEADERS

This edition's Cardiology Leaders profiles cardiac imaging expert, Prof. Valentin Sinitsyn, co-founder and Vice-President of the European Society of Cardiac Radiology. A graduate of the Sechenov 1st Moscow Medical Institute in 1978, he obtained his first doctoral thesis from the cardiology centre in 1989 (MD) and second (MD, PhD) in 1995. In 1994 he became professor of radiology. Today, he is chief of the radiology department in the Federal Centre of Medicine and Rehabilitation. In this interview and profile of his career to date, he shares his predictions for the future of cardiac CT and MR and expresses the need for strong leadership amongst cardiac radiologists.

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## CARDIOLOGY MANAGEMENT

#### News & Views

#### **Spain Takes Over Presidency of EU Council**

Spain has pledged to drive forward the realisation of the European Research Area (ERA) during its six-month Presidency of the Council of the EU, which started on January 1st. Innovation and equality are at the heart of the Spanish Presidency programme, explained Science and Innovation Minister Cristina Garmendia who added, "Promoting the construction of the ERA is key to the success of this programme. It is only by having a common shared space for knowledge, the ERA, in which scientists and ideas can move freely, that research and innovation will be able to act as engines for economic and social progress over the coming decades. For this reason, they should be at the heart of European Union policies."

Spain has identified three "axes" to drive the ERA forward: integration, involvement and inclusion. The integration axis refers to the importance of integrating research and development (R&D) policies into other policies - and specifically into the EU's strategy for 2020. Through the involvement axis, Spain will seek to ensure that all instruments supporting R&D and innovation in Europe, whether they are regional, national or pan-European in nature, address the major challenges faced by society today. These include climate change, the search for new sources of energy, ageing and disease, and globalisation. Finally, the inclusion axis focuses on the role science and innovation can play in promoting social cohesion and tackling poverty and exclusion.

Writing on CORDIS, the Spanish Presidency explains "Europe has the duty and the opportunity to lead the battle against inequality and to put science and technology to use in this fight". Looked at more broadly, Spain's priorities for the next six months include: consolidating Europe's social agenda, paying special attention to gender equal-

ity and the fight against domestic violence; getting out of the economic crisis; energy security and climate change; creating a safer EU, particularly with regard to the challenge of immigration; and enabling Europe to speak with its own voice on the international scene. Spain will head up the EU Council for the first half of 2010, before handing over the reins to Belgium on July 1st.

Together with Hungary, which will hold the Presidency in the first half of 2011, Spain and Belgium have put together an 18-month work programme. In it, they promise to "take full account of the importance of research and development and innovation in the renewal of the post-2010 Lisbon Strategy". In addition to the creation and governance of the ERA, priorities identified by the trio include the analysis of the mid-term review of the Seventh Framework Programme (FP7) and the implementation of joint programming. In particular, the Presidencies are keen to emphasise the importance of the regional dimension of innovation and research policies. They also highlight the importance of making research careers more attractive and attracting the world's best brains to Europe.

The three nations pledge to closely follow the creation of the first knowledge and innovation communities (KICs) under the European Institute of Innovation and Technology (EIT). Finally, they say they will "closely monitor" progress on the development of the pan-European research infrastructures identified by the European Strategy Forum on Research Infrastructures (ESFRI). Meanwhile, looking back on the Swedish Presidency, which ran for the second half of 2009, Sweden's Minister for Higher Education and Research, Tobias Krantz, commented, "It has been incredibly interesting to be allowed to lead a number of important processes during the autumn. Long-term issues cannot be solved in only a few months, but I have spoken to my Spanish counterpart and I have been given to understand that the Spanish Presidency will continue work on a lot of the issues that we have started. That feels good."

## Commissioner Promises "Action and Delivery" for Research, Innovation and Science

The European Commissioner designate for Research, Innovation and Science, Máire Geoghegan-Quinn, pledged to move research, innovation and science "to the heart of European policy" in a hearing at the European Parliament. Speaking to the European Parliament's committees on Industry, Research and Energy (ITRE) and Culture and Education (CULT), the new Commissioner designate said that the European Union must become an Innovation Union. "Knowledge, research and scientific excellence is a cornerstone of innovation", she stated. "In the new economy, refined knowledge will replace crude oil as the economy's prime motive force."

During a confident performance, Mrs Geoghegan-Quinn said that if approved as Commissioner, her policies would focus on three main areas: completing the creation of the European Research Area (ERA), addressing societies' grand challenges, and creating an innovation research culture. In her opening speech, she also highlighted the importance of bringing more small and medium-sized enterprises (SMEs) into the EU's research programmes, and leveraging additional EU funds, such as the Structural Funds, for research. After the speech, the floor was thrown open to questions from the Members of the European Parliament (MEPs), and during her grilling, Mrs Geoghegan-Quinn gave an idea of the kind of Commissioner she would be.

Asked whether she would be a Research Commissioner who comes up with the big



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Tonino PA, De Bruyne B, Pijls NH, et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med. 2009;360(3):213-24.

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we have available, she replied forcefully: "I'm a politician, not a civil servant. I'm going to use the instruments that are already there to ensure that we deliver research to where it is needed." Describing herself as "a doer", she continued, "I will be robust in pushing this forward." She concluded by expressing her desire for 'action and delivery". Responding to a question on how she would obtain a large block of funding for research during the next round of EU budget negotiations, she said, "I'm up for the challenge. I've done it before in government. I will fight to get as much as I can." In reply to a query on how she would attract more people to science she said, "We should make science sexy. Do we have celebrity scientists? We should have."

idea or one who improves the instruments

#### **Further Reading**

- Website of the Spanish Council Presidency: http://www.eu2010.es/
- Spanish Council Presidency pages on CORDIS: http://cordis.europa.eu/spain/ presidency2010/home\_en.html
- 18-month work programme of Spain, Belgium and Hungary: http://www.eu2010.es/comun/ descargas/ProyectoProgramaTrxo-16771.en09.pdf

#### ICT Profiles Supports R&D Players to Find Appropriate Partners

Austria has launched the new on-line directory called ICTprofiles, which provides the user with a professional and entirely web-based platform for successful partner searches. ICTprofiles allows its users to find collaboration partners with a focus on Information and Communication Technology (ICT):

- In all relevant research areas (e.g. FP7);
- In commercial areas, and
- In governmental areas.

This directory enables R&D players from all over the world to review the R&D core com-

petencies and publications of the Austrian Information and Communication Technology community. The clearly represented profiles inform the visitors about expertise, interests and aims of the organisation.

In order to ensure the continuous high quality of the database, all published profiles are updated on a regular basis. In the past few months approximately 300 Austrian R&D profiles have passed the quality check and were published by the Austrian ICT National Contact Point, who is also the operator of this database. A newly developed search mechanism allows expeditious searching or browsing through more than 60 different ICT sectors. In addition, a keyword search application is available, which is progressively filled up by the user and is monitored by an operator.

Interested parties benefit from this broad pool of R&D profiles for potential strategic partnerships and international R&D cooperation. Also, all previous involvements in EU funded projects of the potential partners and their contact details are published in detail on this database. ICT profiles is a free-of-charge on-line service and is operated by the Austrian Research Promotion Agency (FFG), European and International Programmes Division.

#### **Further Reading**

- The European Parliament's hearings website:http://www.europarl.europa. eu/hearings
- European Commission website on the Commissioners designate:
   http://ec.europa.eu/commission.des
  - http://ec.europa.eu/commission\_designate\_2009-2014/index\_en.htm

#### **Telemedicine Forum Seeks Contributors**

The Telemedicine Forum at ePractice.eu is an initiative sponsored by the European Commission to help all practitioners involved in telemedicine services in Europe to meet and share their experiences and knowledge, and to ask and to provide support. The community is open to practitioners from European national and re-

gional administrations, from public and private organisations, including stakeholders' representatives (i.e. patients, professionals, industry) and from academia. Involvement of regional/local telemedicine providers is particularly welcomed. Hopefully such a variety of stakeholders will provide different contributions, approaches and points of view.

The Telemedicine Forum is an open space to express opinions and exchange knowledge in which members are encouraged to provide contributions and participate in the discussions and events. It is not an official Commission site. The community is mainly focused on legal, organisational (including sustainability, business models) and technical aspects of telemedicine services.

#### **Further Reading**

• http://www.ictprofiles.at

#### SmartPersonalHealth: a European E-health Project

Smart Personal Health is a new European Initiative to promote awareness about issues and challenges related to personal health systems interoperability, from technical to organisational and legal aspects.

More and more devices and applications are coming onto the market. They are often recommended by doctors and health insurers to help patients monitor their health and wellness. These "personal health systems" (PHS) are one of the key elements of the growth of European e-health. PHS will only realise their true potential if they are interoperable: a device from one vendor should work seamlessly together with another and other e-health applications.

Stakeholders must understand and support the challenges of personal health systems interoperability. These challenges are technical, organisational and legal.

The European Commission has called for action to support a wider understanding of interoperability amongst key stakeholders and has funded a Support Action to promote interoperability among personal health systems and to other e-health systems. The project SmartPersonalHealth started on January 1, 2010 and will run for one year.

Key activities of SmartPersonalHealth will include three thematically focused regional stakeholder workshops and one central pan-European PHS Interoperability Conference. Further networking and dialogue with healthcare providers, patients, industry, insurers, standard development organisations will be carried out. The Continua Health Alliance web portal will provide relevant information. The workshops and related networking will result in a report addressed to the European Commission highlighting the current status, concerns, barriers and incentives to accelerate the development and adoption of interoperable PHS systems. Recommendations for interoperability promotion will be proposed to the EC, national governments, stakeholder groups and industry.

The programme is run by Continua Health Alliance, IHE-Europe, ETSI and Empirica, coordinated by The Centre, and funded under European Commission's FP7 Programme.

#### **Further Reading**

• http://sph.continuaalliance.org

#### **HL7 Transmits Genetic Results to EHR**

Health Level Seven (HL7), the global interoperability standards body for healthcare IT, has announced that its messaging standard has successfully coded genetic test results from a lab and transmitted them to an electronic health record for the first time.

The HL7 Version 2 Implementation Guide details how to structure a genetic test result into the EHR using HL7 Version 2.5.1 and covers the reporting of genetic test results for sequencing and genotyping based tests.

The implementation guide was used by The Partners HealthCare Centre for Personalised Genetic Medicine (PCPGM) and the Intermountain Healthcare Clinical Genetics Institute to obtain genetic test results and transmit them directly through a computer interface from PCPGM to Intermountain Healthcare to the EHR.

Stan Huff, chief medical informatics officer for Intermountain Healthcare and HL7 board member, said: "The project is among the first in the country that will create a standardised advanced electronic patient record system containing genetic data.

"This may lead to electronic health records of the future, which would support treatment plans that are tailor made for each individual-right down to their DNA."

This may lead to electronic health records of the future, which would support treatment plans that are tailor made for each individual, right down to their DNA."

Huff worked with PCPGM for 14 months to build the framework for receiving test results and integrating them into an EHR. At the same the time the Partners team also developed a lab reporting system that would create and send out the test results message through a centralised interface hub. Any lab or EHR that implements the HL7 standard can now interface with the hub.

Using the guide, Intermountain and Partners Healthcare are now working to make the genetic information available within the EHR, including clinical decision support, linkage to clinical genetic knowledge bases and drug order entry.

#### **EU Funds Advances** in **Grid Computing**

A team of European researchers from the KNOWARC ('Grid-enabled know-how sharing technology based on ARC services and open standards') project, which received almost three million euros in funding under the 'Information Society Technologies' (IST) Thematic area of the EU's Sixth Framework Programme (FP6), have developed a revolutionary middleware programme.

The advanced middleware enables computers running any operating system to access the distributed computers comprising the grid in a straightforward, cheaper and efficient manner. "Grid computing allows users to access the computing resources of many different machines distributed around the world," said Prof. Farid Ould-Saada from the Department of Physics at the University of Oslo in Norway, and the coordinator of KNOWARC.

Professor Ould-Saada pointed out that with the new middleware, "Getting access to the grid should be as simple as installing a new browser to get on the internet". KNOWARC project partners improved "advanced resource connector" (ARC) middleware currently available to users. ARC middleware provides interoperability between computing systems, architectures and platforms. ARC middleware will become the standard installation model for the popular Debian and Fedora distributions of open source operating system Linux, according to the researchers.

NORDUGRID, a grid research and development (R&D) venture designed and developed ARC, i.e. the 'free grid', middleware. The EGI\_DS (European Grid Initiative Design Study) project, which has clinched 2.5 million euros under the Seventh Framework Programme (FP7) has picked the software to be included in a sustainable European supergrid infrastructure.

Professor Ould-Saada concluded: 'In a matter of years, I hope to see resources and storage being as easy to access remotely as information is on the internet today.'

#### **Further Reading**

- KNOWARC: http://www.knowarc.eu
- ICT Results: http://cordis.europa.eu/ictresults

## Perfecting the Digital PACS Experience at Groene Hart Ziekenhuis



Nestled in a particularly beautiful area of the West Netherlands, the historical city of Gouda is home to the Groene Hart Ziekenhuis (Green Heart Hospital). Spanning four main sites, the Groene Hart is a medium-sized general hospital providing care to a local population of 450,000 people. Housing 441 beds the hospital employs some 150 doctors and, as an established user of Carestream Health products, it was the ideal European launch point for the new CARESTREAM Cardiology PACS.

Launched in 2009, the CARESTREAM Cardiology PACS offers a single integrated platform for diagnosis, reporting, storage and review, creating a closed-loop information cycle that greatly improves efficiencies and removes the potential for errors caused by multiple data entry points. Working in synchrony with the Hospital Information System, Carestream Health's PACS takes patient information from a central database and duplicates it across every record or entry made about that patient—no more lost records, broken videotapes or corrupted CDs.

Carestream Health spoke to Ralph Wagter, the resident ICT consultant at the hospital. The Cardiology department saw the benefits in implementing a digitised workflow and asked the ICT department to help select and implement such a workflow.

Ralph describes the scope of the project in Cardiology; "The plan was to digitise ultrasound and cath lab, previously stored in analogue form on VHS and CD. We have a large archive of VHS tapes that necessitated lots of time spent searching through for patient records; obviously a manual process that was both time-consuming and carried the potential for error." Committed to the ideals of best practice and efficiency creation, Ralph was impressed with the promise of CARESTREAM Cardiology PACS: "We saw what Carestream Health did for us in Radiology which, although a very different type of set-up, relies on the same basic tenets that we wanted to translate to Cardiology—digital imaging, processing, report and review."

The Groene Hart discovered through its own research that Carestream Health was the only vendor prepared to offer an

integrated system. Ralph explains: "The potential to integrate the systems was the most exciting part; every piece of information is stored in a central hub and is instantly accessible from a single browser located anywhere in the hospital, cardiology and radiology alike. Carestream Health delivered this flexibility, working with us to create a bespoke system that perfectly meets our needs."

Carestream Health's application specialists worked on-site to perform the installation, a complex process that began in May 2009 and was rolled out in September 2009. As in any environment dealing with confidential data it was essential to ensure thorough checks and beta-testing took place before going live with real data.



"We saw what Carestream Health did for us in Radiology which, although a very different type of set-up, relies on the same basic tenets that we wanted to translate to Cardiology—digital imaging, processing, report and review."

Ralph Wagter, resident ICT Consultant at Groene Hart Ziekenhuis.

"Carestream Health delivered

flexibility, working with us to

create a bespoke system that

Ralph Wagter, resident ICT Consultant at

perfectly met our needs."

Groene Hart Ziekenhuis.





Initial system training was conducted by Carestream Health and included a cross-section of key users from the pool of Cardiologists and Technicians. From here a 'train the trainer' programme was successfully rolled out providing a two-tier benefit system that not only compounds the knowledge of the recent trainee but also enables him to pass on expertise to his colleagues using contextual cues and examples that an

external trainer would be unaware of. The net result is a robustly trained department who feel a sense of shared responsibility for ensuring the success of the system.

Carestream Health has since provided additional support both on- and off-site and this will continue, giving Carestream Health the opportunity to learn from the experiences at the Groene Hart and work on further system developments based on real rather than simulated client experiences.

The PACS necessitates some subtle changes to working practices. Previously Cardiologists would dictate reports that would then either be stored in tape form for future reference or typed up and stored in hard copy with a patient's file. Using CARESTREAM Cardiology PACS all of this data is held in digital format, facilitating its use and review from any authorised viewing point. This precipitates an administrative shift that different departments will handle in different ways and as Ralph describes: "At the Groene Hart it's involved an element of change management, working with people to show them how the change will benefit them and to help them manage their workload positively. Our long term aim here is to enable remote access which will make this easier still."

The experience at Groene Hart is a perfect example of what can be achieved using CARESTREAM Cardiology PACS. A 27-step workflow has been contracted to just 8 steps through intelligent combinations made by combining different systems, which was not possible without the CARESTREAM Cardiology PACS. Whilst it's impossible to convert this to a direct time or cost saving, the correlations

> between a contracted workflow, financial economy and greater accuracy-streamlining the potential for error—are obvious.

In terms of its impact on patient care, the CARESTREAM Cardiology PACS enables much more intuitive reviewing and reporting; comments that a patient makes during a consultation can be discussed and immediately assessed using the live data taken from the scan.

Patients also have the option to take home a copy

of their CD and, in the absence of a national imaging network, another hospital can request and receive a CD with a significantly faster turnaround—all huge positive steps in terms of improving communication and maintaining high standards of patient care.

Cardiology PACS; "PACS could be adapted for use with any this technology spreads itself, the more successful it will become." Specifically at Groene Hart, the next step is to roll out PACS to ECG and work on delivering remote access to the hospital's consultants, making the system work ever more efficiently and completing the transition from analogue to digital.

Ralph describes his predictions for the potential of CARESTREAM documents or streams of information, basically anywhere that is imaging and storing information could benefit and the wider that

> For more information visit cardiopacs.carestreamhealth.com





#### APPLICATIONS OF TELECARDIOLOGY

#### Recommendations for its Use in Practice



AUTHOR

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Cardiovascular diseases play a major role in general morbidity and disability, representing one of the major burdens to our healthcare system. Telemedicine can reduce the pressure on medical experts, who are limited in number, and extend their expertise to patients in isolated or remote locations. Telemedicine appears particularly promising in cardiovascular disease, because early, tailored interventions are extremely cost-effective in terms of life-saving and functional recovery.

Telecardiology has advantages for the individual patient in the interaction between primary and secondary care. In addition, general practitioners (GPs) gain educationally and hospital follow-up appointments may be reduced in number, because the GPs can handle more advanced medical problems.

Telecardiology has been widely used in the diagnosis of arrhythmias and for the management of patients with chronic cardiovascular conditions. It is important to note that in many cardiovascular conditions, such as acute coronary syndromes, the opportunity to offer prompt diagnosis and treatment will improve outcomes in terms of mortality and functional recovery.

#### **Technology**

In a telemedicine network there are three basic components: the Electronic Personal Record (EPR), digital devices and telecommunications. The main aim of the system is to collect specific and systemised patients data from different medical centres and to

organise them in the best possible way in order to make the appropriate medical decisions. The information technology of the telecardiological system uses different solutions. An EPR could be built in a open source/free software; the most popular solution for internet applications is the threelayer client-server application; such a choice ensures that an EPR can be used by various medical centres cooperating with each other and implementing e-Health applications. The telemedicine platform handles all the medical information and integrates it with the EPR, which collates all healthcare data in a dynamic way. The characteristics of the platform should be:

- Usability;
- Web based architecture;
- Direct access to information via browser;
- Access to information through cross-links;
- Flexibility;
- Dynamic dealing of medical/ health data (easily customisable);
- Interoperability;
- Communication support, as the main standard communications systems, to external server to server and/or platforms of technology providers;
- Health information systems;
- Biological signals acquisition platforms;
- Adherence to standards;
- Semantic standardisation;
- Terminology and coding standardisation, e.g. ICD (ICD-9-CM), LOINC, SNOMED, UHID, AIFA;
- Syntactic standardisation, e.g. HL7,(CDA, Clinical Document Architecture), DICOM, and
- · Modularity and extensibility.

The type of connection will affect the speed of transmission and the quality of the video-conference. Standard telephone lines (PSTN) or the patient's mobile phone are enough for the transmission of a one-lead electrocardiography (ECG). Digital lines

(ISDN) may be required to transmit signals from more complex devices (e.g. multi-lead ECG or video). Digital subscriber lines (e.g. ADSL) for high-speed internet connections can be used for every type of video, signal and images in cardiology.

#### **Telecardiology Applications**

#### 1. Pre-hospital

Telecardiology can be used to support the treatment of acute coronary syndrome by emergency medical services. Studies have shown the feasibility of obtaining a 12-lead ECG during the pre-hospital period. Diagnostic quality ECGs can be successfully transmitted for approximately 85 percent of patients with chest pain who are eligible for 12-lead ECGs. Pre-hospital 12-lead ECG transfer improves pre-hospital diagnostic accuracy for patients with a final hospital diagnosis of AMI, angina or non-ischaemic chest pain.

The guidelines of the American Heart Association for cardiopulmonary resuscitation and emergency cardiovascular care recommend the use of out-of-hospital 12-lead ECG diagnosis in urban and suburban paramedic systems.

#### 2. In-hospital

In-hospital telecardiology is used between small hospitals in rural regions and main hospitals. Telemedicine has the potential to improve access to echocardiography diagnoses in the intensive care unit, emergency room and newborn nursery. In some centres, urgent echocardiography is performed during the weekend, evening and overnight to assess ventricular function, ischaemia, pericardial effusion, valvular disease and heart donor status. Several studies have reported close to 100 percent diagnostic agreement when live telemedicine interpretations were compared with videotape interpretations, and the mean time from the echoimages recording to reporting was significantly shorter than the traditional method. Live transmission of neonatal echocardiograms by paediatricians led to an immediate change in management of patients including transport to the main clinic if necessary. More recently, videoconferencing for the transmission of echocardiography data has been also proven useful for the assessment of children with suspected cardiac diseases.

#### 3. Post-hospital

#### I. Teleconsulting between GPs and specialists

General practitioners deal with increasing numbers of patients with cardiac disease, who have often been discharged early from the hospital and whom the GP must manage by themselves. In this case, second opinion consultation may be helpful. Telemedicine has mainly been applied in the diagnosis of arrhythmias, or used directly by GPs as an alternative to ambulatory visits for patients with chronic conditions or systemic hypertension. The advantages include early diagnosis and tailored therapeutic interventions, home management of conditions, availability of specialist teleconsultation out of the hospital, and improvement in the appropriateness of hospital admissions and referrals to the emergency department.

#### II. Home telenursing for chronic cardiac diseases

Chronic cardiac diseases such as chronic heart failure benefit from a multidisciplinary approach that can reduce hospitalisation and improve the patient's quality of life, while lowering costs for the national health service. Home telenursing is an integrated approach that involves the patient, the family, the GP and specialised cardiac centres. Real-time transmission of objective data (physiological data and biological signals) in association with personal data given by the patient is a new approach to the problem. Telemonitoring allows the follow up of patients for long periods. Indeed, telemonitoring and teleassistance through nurse, specialists and GPs can constitute a disease management programme.

There is some evidence that multi-dis-

ciplinary management and home-based intervention can reduce readmission rates and length of hospital stay in chronic cardiac patients. However, many studies have involved few patients, often they were not randomised, and also used different types of telemonitoring in combination with the multidisciplinary management of chronic heart failure, making it difficult to determine to what extent beneficial outcomes were due to telemonitoring.

Different results have been reported for mortality, but in no study was this the primary endpoint. Very few studies have assessed the cost-benefits of telemonitoring but implementation of such a programme was found to decrease annual medical costs compared with the previous year in some cases.

"Telecardiology has yet to reach maturity, but the evidence to date indicates that it has made a good start."

III. Diagnosis for arrhythmias, monitoring of pacemakers and implantations of cardioverter defibrillators (ICDs)

Palpitation is a common symptom that sometimes results from a substantial cardiac arrhythmia. Establishing the cause of palpitations may be difficult because historical clues are not always accurate. A 24-hour Holter monitor is usually used, but the yield of this instrument is low in patients whose symptoms occur infrequently. Another instrument used to study palpitations is a transtelephonic event recorder.

Transtelephonic pacemaker monitoring is accurate and reliable and reveals a significant quantity of unpredictable abnormalities, such as failure to sense and capture tachyarrhythmias that necessitate a change of pacemaker mode. As a result of recent trials on prevention of sudden cardiac death, the rate of ICD implementation is increasing, in particular with the advent of biventricular ICDs for patients with heart failure. Remote ICD interrogation allows frequent, convenient, safe and comprehensive monitoring.

Device- and patient-related problems were reliably detected and reduced the frequency of outpatient visits. Patients are satisfied with the convenience and easy use of the system.

#### **Other Applications**

In paediatric patients with suspected cardiac disease, a telephonic stethoscope can accurately distinguish between functional and organic murmurs and can be used in remote areas where paediatric cardiologists are not present. Moreover, control magnetic resonance (MR) imaging in complex cardiovascular procedures was developed from a remote location and advanced processing of diagnostic images in stereographic display of CT and MR data were performed by an Italian group from Pisa.

#### **Conclusions**

Despite the diversity of models and the lack of systematic research, successful telecardiology programmes exist. One barrier to more widespread implementation is that there are many different software, hardware and telecommunications options, but none are designed specifically for cardiology. Thus each component may function well in isolation, but integrating the components is more difficult, e.g. a call centre may receive ECGs from different devices sent via different telecommunication modalities. Reimbursement for telecardiology consultation is also limited and may discourage many physicians from participating.

Telecardiology is one of the fastest-growing fields in telemedicine. There is already a significant quantity of published clinical data, with some randomised multi-centre trials to answer the most important questions in definitive way. The contribution of telecardiology in some fields such as emergency and chronic care undoubtedly improves the quality of healthcare and helps contain rising costs. Telecardiology has yet to reach maturity, but the evidence to date indicates that it has made a good start.

A full set of references is available on request to the Managing Editor at edi.torial@cardiologymanagement.eu



**COVER STORY: E-HEALTH - NEW HORIZONS FOR CARDIOLOGY** 

#### THE ROLE OF THE EHR IN RESEARCH

#### **Applications Beyond Clinical Care**



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Conceptually, the Electronic Health Record (EHR) is intended be a lifelong collection of health-relevant data for a consenting person. The main purpose of the EHR is to assist medical care by providing health professionals with the information for diagnosis and therapy where, when and how it is needed. This is particularly important in the highly specialised and sometimes fragmented health sector of today, where a patient is seen and treated by many different health professionals.

#### Uses of EHR Go Beyond Direct Medical Care

Besides direct medical care, there are many potential secondary uses of the data in a health record - streamlining of organisational processes, data for management and planning in the healthcare system, epidemiology, quality control, medical research, etc. In e-health, the EHR is part of an integrated system of actively distributing and monitoring the information in the EHR. On a small scale this could mean an alert to a physician that patient data suggests a contraindication to a prescribed drug or on a national or even international scale an alert to health authorities that an abnormal increase in the incidence rate of an infectious disease in some region might need attention and intervention.

#### **Controlling Misuse**

Of course there are also potential misuses of the EHR infringing the patients' and

health professionals' right to privacy. This shows that the policies about who might legally access which parts of the EHR for what use, and who (e.g. the patient) might deny or grant access to (specified parts of) the EHR and the methods to enforce these policies are of vital importance for the implementation of the EHR.

#### **Clinical Research/Clinical Studies**

Today, the terms clinical research and clinical study are almost synonymous, because the well-designed clinical study is the most reliable means to test a clinical hypothesis and to get dependable results. To achieve that, the study must meet a number of requirements: the hypothesis must be known beforehand, random assignment of patients to test group and control group, blinding and double blinding, clear definition of inclusion and exclusion criteria and strict formal requirements for documentation, etc.

#### Integrating Clinical Studies in an E-health System

In principle, it should be possible to integrate clinical studies in the e-health system, because a considerable part of the data needed for a clinical study are also part of the EHR and the additional data particular for the study are usually elicited in a clinical environment and could be integrated in the data capture protocols of the EHR for the time of the study. In reality for a multicentric study this is almost impossible because of differences in terminologies, policies, data formats, regulations, interfaces, etc.

Recent literature has listed the integration of medical record systems and clinical trial databases as one of the most important challenges for medical informatics. In analogy to the alerts described in the first paragraph, the e-Health System could give an alert if a patient matches the inclusion criteria of a current clinical study, thus assisting patient recruitment.

#### Clinical Research Outside of Clinical Studies

For different reasons, clinical studies are not always feasible. As a rule of thumb, a study cannot be performed if the potential risk outweighs the potential benefit for the patient. To give a classic example: the hypothesis that an increase in the incidence rate of congenital malformations is due to a newly introduced drug cannot be tested by a prospective study! In such a case the only possibility is a careful analysis of already existing datahence the importance of a comprehensive documentation even of 'routine' cases.

In this case, one could as a first step retrieve all babies born after the introduction of the drug and then build four groups: baby has no malformation and mother did not use the drug, baby has malformation and mother did not take the drug, baby has no malformation and mother did use the drug, baby has malformation and mother did use the drug.

In an integrated e-health system, such a task should not be too complicated (except if the drug is sold over the counter) and statistical analysis would give a strong indication of how to proceed (from removing the

There is no question that e-Health systems including the EHR could and will be an important data source for clinical research, supporting clinical studies, testing clinical hypotheses and, even more important, generating hypotheses (e.g. about possible causes for diseases or different responses to treatments) from a linked analysis of so far unrelated data in particular, including genomics and proteomics.

drug to dismissing the hypothesis). An e-Health system could even recognise the increased rate of malformations automatically, give a warning and then assist in the search for possible causes (finding differences in the anamnesis of babies with and without malformation). In most existing systems, only the first part – finding the mothers of babies with and without malformation, could be automated - but many different databases would have to be involved.

Results that are not obtained by planned clinical studies are more likely to be distorted by different forms of bias. Still, the physician facing a patient must make a decision on how to proceed, even if information is incomplete and the therapeutic options are not perfectly validated. Clinical science cannot disregard any information that may help the physician to make a rational decision.

#### The Role of Classification in Clinical Care and Clinical Research

Each patient is a unique individual and must be treated and documented as such. Each patient must be put in a class for rational, evidence-based treatment. Let us start with the second of these two seemingly contradictory statements. Experience leads us to expect that a treatment that was successful in one case will be successful in a similar case. How is 'similar' defined? The two cases are not too different with respect to parameters that are relevant to the outcome, e.g. age, gender, stage of the disease, condition of the patient etc.

With these parameters, one defines classes of similar cases (a typical example is the classification of tumour stages) and these classes are the basis of clinical studies, treatment protocols, etc. If a tumour patient comes for treatment, the type and stage of the tumour is determined and the appropriate treatment protocol is applied.

Although this protocol has been found to be the most effective one for this class of patients, results are not uniform, some patients do not respond and relapse or develop metastases and might have needed a different treatment. Scientists do not attribute these differences to mere chance, but to causal chains that are not yet understood.

It is therefore a constant aim of medical science to find these causes, the hidden parameters that make the difference and to refine the classes accordingly.

An e-health system could be used to find patterns associated with different responses to the treatment, provided that as many findings as possible had been collected, even if they were seemingly unrelated to the clinical problem. So, even if the patient is put in a class to determine the treatment, he/she must also be documented as an individual. Needless to say that in the direct communication with health professionals, the patient must always be seen as an individual person and not merely as a case. It is likely that many hidden parameters mentioned above may be attributed to differences in the genome or proteome. The linking and common analysis of genome/proteome data with clinical data is one of the big challenges in medical research and will require sophisticated and standardised databases within the e-health system.

#### **Medical Records**

The classical medical record was/is a heterogeneous collection of handwritten or typed notes from different sources about anamnesis, diagnostic and therapeutic procedures and results, discharge letters, images, lab results, etc. with a relatively free format. Patient ID or name, was the only criterion for direct retrieval. The record was for human use only and the content had to be scanned visually to extract any information. Still, as a basis for information about the individual patient it was remarkably successful.

The first electronic records were not meant to replace the paper record, but to complement it with a kind of electronic summary consisting mostly of codes denoting more or less complex medical entities. From the point of view of research they did allow for some calculations, frequencies, correlations etc, but for most instances they had the important task of case finding, selecting those cases that were relevant for a problem. Then one had to retrieve those records and extract the details for the scientific analysis.

On a small scale, EHRs could mean an alert to a physician that patient data suggests a contraindication to a prescribed drug or on a national or even international scale an alert to health authorities, that an abnormal increase in the incidence rate of a infectious disease in some region might need attention and intervention.

The EHR aims to replace the paper record. This has become a possibility for two reasons: the processing power and the storage capacity of IT systems has increased tremendously and almost all the data are now captured in digital form because IT has been integrated in imaging devices, labsystems, measuring devices, etc. and virtually every report is written with digital text processing.

#### **Form Follows Function**

The medical record has one main function, serving medical care by providing the necessary information to the different health professionals treating the patient and many secondary functions from billing to research. In the first case the system merely presents the data for human interpretation, in most of the secondary uses the system is supposed to interpret and process the data directly and therefore needs a formalised representation (a code) of all relevant medical concepts.

Examples are ICD (International Classification of Diseases) or SNOMED (systematised nomenclature of medicine) but in reality, codes are often local (and not explicitly seen as codes) defined as input forms with menu items, etc. Choosing a code is a classification of the patient, which means abstracting from seemingly irrelevant details. As an example in many systems you have to select either female or male (rarely a third option is possible). But if the patient does not fall in one of these groups either physically (e.g. hermaphrodite) or mentally (e.g. transgender) this should be documented in the EHR because it is relevant to address him/she as an individual.

The functions of the EHR pose sometimes conflicting requirements to the documentation. In particular, when dealing with human interpretation of findings (e.g. a radiologic report describing the position of a tumour or the abnormal run of a vessel) or human communication (e.g. describing the anamnestic details given by a patient in a psychiatric case) it is difficult to replace natural language by codes without losing important information (by the way, imagine a clinical conference where participants use only SNOMED codes to discuss a complex case).

#### **Challenges**

There is no question that e-health systems including the EHR could and will be an important data source for clinical research, supporting clinical studies, testing clinical hypotheses and, even more important, generating hypotheses (e.g. about possible causes for diseases or different responses to treatments) from a linked analysis of so far unrelated data in particular including genomics and proteomics.

In addition to the necessity to define and implement data protection, communica-

tion standards, etc. there is an urgent need to develop a medical ontology allowing a clear and standardised representation of medical concepts including temporal and spatial relations. In designing an information system for e-Health the needs to classify patients in groups for therapy and data reuse for e.g. research on one side and to retain and document the individual details on the other side must be carefully balanced. The same is true for the use of natural language for human communication and classifying codes for selection therapy protocols and other secondary uses.

#### **OLDES & E-HEALTH FOR THE ELDERLY**

#### An Affordable and Customisable Telecardiology System



CARDIOLOGY MANAGEMENT

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#### Background on Telemedicine-Related EU Policies

A European Commission Communication, adopted on the 04/11/2008 (COM – 2008 - 689 final), advocates the development and use of telemedicine services, including diagnosis, treatment and monitoring at a distance across Europe. The Communication highlights how, in an ageing Europe, where more and more citizens live with chronic health diseases, telemedicine represents an important tool. Developing reliable and sustainable systems, offering consistent effectiveness, interoperability and compatibility with national care systems should become a key means for garnering social and economic benefits throughout the European terri-

tory in the short to medium term. The OLDES project, through its customisable, low-cost and collaborative approach, tackles the challenges proposed by this European legislation, facilitating broader inclusion and providing improved public services and quality of life to citizens, securing at the same time, lower future social security costs. The details of this project are reported below.

The European "Older People's e-Services at Home" (OLDES) project, funded by the sixth EU Framework Programme, aims at tackling some of the challenges that ehealth for the elderly has to face today, due to exponential growth in the ageing population in Western European countries and e-Care solutions scrambling to create adaptable solutions to different medical situations and typologies of diseases. Developing a comprehensive solution to these demands is quite complex, considering the personal needs and constraints of the individual patient, as well as the role and interests that different stakeholders have in such a dimension. In the context of the OLDES approach, e-Care system stakeholders include:

- I. Health providers and social carers;
- II. Those in need of care and

their families;

- III. Volunteers and related associations; and
- IV. Service managers, commissioners, policy makers, industry and the research community.

The approach proposed by OLDES, based on concepts such as participative design and co-production, foresees the development of an accessible and logical platform for the elderly and the involvement of potential interested actors not only in the implementation of the system, but also in the design and validation phases. The use of a low-cost PC (OLDES is based on a low cost easy-to-use, plug and-play system costing around 100 euros per person) in the functional architecture of the platform, combined with essential telesupport and telemedicine services, make OLDES a viable model for future similar service providers and regional social services interested in setting up a programme for remote cardiological services for the elderly.

#### **Context**

One of the most significant problems that actors in such municipalities, healthcare

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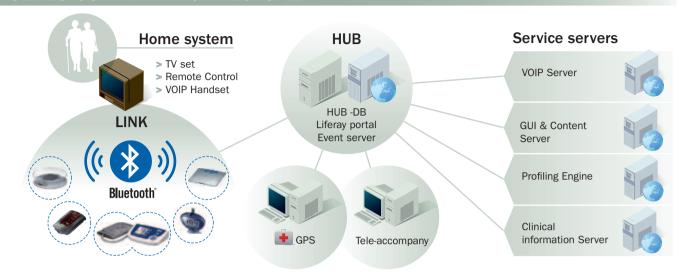
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#### COVER STORY: E-HEALTH - NEW HORIZONS FOR CARDIOLOGY

#### **OLDES CURRENT ARCHITECTURE**



providers and other related service providers have to face in creating e-Care systems is presented by the different kinds of audiences that need these services, and the need to tailor them through affordable and accessible services. If such systems are to be strongly grounded in practice (providing stable and reliable monitoring mechanisms), they also have to be sufficiently generic to be adaptable to different social and medical contexts. With this premise, attempts to provide patients such as the elderly, with high levels of independence through easyto-use and customisable systems, plays a crucial role in the design of e-Care systems. Thus, the design of such a platform (e.g. graphical interface, integrated devices, sensors, functionalities) has to be very well analysed and conceived in advance, in order to efficiently put older people at the centre and make their needs the main priority in all related developments. As such, OLDES provides one such remote healthcare model that has widened the number and typology of potential users.

#### **Platform Design**

Given the lack of familiarity of the elderly with technological devices, the usability and accessibility-related aspects of e-health systems have always represented an important dimension in the implementation of teleassistance platforms. During the last decades much attention has been devoted to this aspect, trying to improve the usability of the systems through customisable solutions potentially replicable in different care situations. In the case of OLDES, the classic keyboard has been substituted with a remote controller, developed especially for the project, in order to ease the interaction between the patient and the system.

A user-centred approach allows testing of the usability and adherence of the proposed tool to elderly needs and capacities, changing the configuration of the Graphical User Interface (GUI) on the basis of the tests carried out alongside the elderly. The whole platform is based on two different levels, namely: a local hub, receiving physiological data and sending them through Voice-IP modality to the central hub, receiving and monitoring information in a personal health agenda, set-up for each patient. Health services and physicians are therefore able to receive, store and compare medical data and, in urgent cases, promptly respond to alarms.

The selected medical devices used for capturing medical data are easy to use for an old person and are as minimally invasive as possible. Data are communicated to the PC through wireless connections (mainly through bluetooth) so as to limit as much as possible the required inputs or technical

interactions by the elderly. The following devices and sensors have been tested in the design and development of OLDES platform: an adapted version of a sphygmomanometer for obtaining elderly blood pressure, ECG belts for monitoring blood pressure, a lifescan for glucose level, together with some scales for weight and daily diet monitoring. Furthermore, some ambient monitoring systems (for patients' home temperature and humidity) are being tested in order to check patients' living conditions, mainly in the summer periods when rising temperatures may have serious consequences for health amongst the elderly.

#### The Pilot Programmes: Telecardiology in Action

In order to test and validate the OLDES platform, two different pilots are currently being implemented: one in Prague focused on 10 diabetes patients and one in Bologna, targeted at 100 patients. With regards to the Prague pilot programme, this is focused on older persons suffering from type-2 diabetes mellitus. In this context, the project offers users the possibility to control their diet, allowing the carer or the physician to check physiological functions and diabetes diagnosis on an "online modality". Since a critical aspect of diabetic compensation is their diet, patients require a strict follow-

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up of nutrient and energy intake, which tends to be a problem, especially for the elderly.

#### **Scale Monitors Food Consumption**

A programmable and interactive scale that is incorporated into the OLDES platform calculates the amount of energy and nutrients in a particular piece of food. Its memory will store data about calories, saccharides, proteins and lipids taken in throughout the day and calculate the maximal daily dose of various food sorts that the particular person is allowed to consume.

This process is implemented though the use of wireless scales installed at patients' homes where the food is weighed and assessed with regards to its nutritional values. Patients are invited to measure their weight once a day, blood pressure three times per day and glucose level three times per day. After data are sent through the OLDES platform, the physician is able to make recommendations or, if necessary, raise medical alarms. The pilot is coordinated by the

Charles University in Prague through the technical support of the Czech Technical University in Prague/CVUT.

Bologna's pilot aims at testing the OLDES platform on a range of 100 patients. Further to the tele-support services provided to the complete range of patients, 10 of these, suffering from cardiological problems, are being monitored through sensors for the remote monitoring of physiological parameters (body weight, blood pressure, blood oxygen saturation, ECG).

The other 90 "testers" of the OLDES tele-support services platform are selected by the social services unit of the Savena District (Municipality of Bologna) together with an ad-hoc established tele-support working group composed of technical representatives of the local partners, while the ten cardiopathic patients are currently under treatment at the Cardiology Division of Bellaria Hospital in Bologna. The main actors involved in this pilot are the Municipality of Bologna, The Local Health Authority of Bologna, the

company "CUP 2000" and the University of Bologna.

#### **Considerations**

Through a 'federated' design, meaning that it spans a number of different agencies and institutions, OLDES supports and offers an innovative and collaborative approach to the delivery of welfare services to the elderly. Following the EU's recommendations (that the benefits go beyond improving patient care and healthcare system efficiency, whereby telemedicine can also make a significant contribution to the EU economy), OLDES is designed to be scalable, highly customisable and governable by service providers, users and commissioners in response to dynamic and emergent needs and priorities. In the OLDES vision, many elderly people can be supported in their own homes by means of networked connections and services, contributing greatly to the quality and the costeffectiveness of their care, and to their independence and wellbeing.

#### GUIDELINES FOR RUNNING A PAEDIATRIC TELECARDIOLOGY SERVICE

#### Children's Memorial Hospital, Chicago, Shares Their Success



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For paediatric cardiologists, telecardiology has become a valuable tool in diagnosing and triaging newborns with suspected congenital heart disease at remote hospital nurseries. The tele-echocardiography programme developed over 15 years ago at the

Children's Memorial Hospital, Chicago, IL, has spawned similar programmes both in the United States and internationally. The continued success of this type of service has relied on several key points:

- Access of both hub and outreach sites to stable, low-cost telecommunications services and videoconferencing equipment;
- Easy-to-use technology for all hospital personnel participating in the programme;
- Appropriate echocardiography equipment;
- The commitment to training by outreach sites; and
- Continuous customer improvements.

A community hospital with 2,000 live births may need the tele-echocardiography service only 150 times per year. Hospital administration commonly resists purchase of complex technology with high capital and operational costs, which requires subsequent ongoing equipment upgrades. Therefore, the price point needs to be affordable and at a break-even point within the first few years.

#### **Developing the Service**

In 1994, the diagnosis of congenital heart disease was made in several inefficient ways, which prolonged the time to diagnosis:

- Transport of the patient to the paedatric hospital;
- Paediatric cardiologist or paediatric sonographer travel to the patient; or
- Echocardiogram sent to the paediatric cardiologist for interpretation.

In addition, sonographers who perform the studies at outreach sites are unfamiliar with specific paediatric scanning techniques and they have limited knowledge of congenital heart disease. Tele-echocardiography decreases the time to diagnosis and allows necessary life-saving treatment and better management of critically ill patients.

The concept of bedside real-time videoconferencing at an affordable cost and with off-the shelf technology was pioneered at Children's Memorial through regional access to Integrated Service Digital Network (ISDN) telephone lines. The partnership with area hospitals was built on a 24/7-service model between cardiac sonographers, the paediatric cardiologist, and the referring physicians managing the patients. A critical component has always been the training of remote hospital sonographers in techniques of paediatric cardiac scanning. This training is more than simple memorisation of the various types of congenital heart disease. It includes thorough interrogation of normal cardiac and abdominal situs with assessment of intra- and extra-cardiac connections using a segmental approach. This same scanning protocol continues to be used today.

#### **Customer Service**

Key components of the success of this service include easy to use equipment as well as the important relationships that are developed between the hub and the outreach hospitals. With a pre-arranged page during the day or on-call, the tele-echo is scheduled. Then the performance of a tele-echo during off hours involves the remote site sonographer taking the ultrasound system with the attached self-contained videoconferencing unit to the patient's bedside. No additional outreach hospital staff support is needed. The sonographer dials the Children's Memorial Hospital paediatric cardiologist on-call at her home unit. After con-

firming the medical information, the echocardiogram is begun, with ongoing dialogue between the cardiologist and the sonographer to ensure that proper views are obtained. Severe heart disease is usually evident within the first few minutes.

A complete study can be finished within 30 minutes. Using the results of the echocardiogram, management decisions are made by the referring neonatologist and the parents receive immediate feedback. A neonatal intensive care unit and a paediatric cardiologist may be many miles apart, yet, timely cardiac diagnosis is accomplished within 45 minutes of the sonographer arriving at the child's bedside, and appropriate treatment can be started.

#### **Training for Success**

Although in many parts of the world an echocardiogram is performed by physicians, in the U.S. the cardiac sonographers perform transthoracic echoes. These skilled allied health personnel complete training and sit for examinations through the American Registry of Diagnostic Medical Sonography. The pass rate on these rigorous examinations for both physics and paediatric echocardiography is about 60%. It is also recommended that sonographers have ongoing exposure to at least 400 patients a year in order to maintain their skills.

Since sonographers at our partner sites are usually skilled in adult echocardiography, but not in paediatric echocardiography, we provide specific on-site training in the mastery of our scanning protocol. Only those sonographers who have successfully completed this training may participate in tele-echocardiography and the on-call service. The videoconferencing provides the needed supervision.

#### **Measuring the Benefits**

A multi-institutional study sponsored by the American Society of Echocardiography demonstrated that telecardiology resulted in decreased time to diagnosis, shorter ICU and hospital stay, and cost savings due to better ability to accurately triage the need for ambulance transport. In addition, ther-

apy could be very specifically tailored to the individual needs of each infant. More than 1,000 cases were assessed in this study and the most significant success of telecardiology has been the lives saved due to the immediate diagnosis and interventional management. Since inception of the telecardiology programme at Children's Memorial Hospital, more than 12,000 telecardiology studies have been done.

Some patients diagnosed using this technology have had critical heart disease requiring immediate medical therapy and ambulance or helicopter transport to the hub tertiary care hospital. Such was the case with baby Matthew, who was being discharged from the normal newborn nursery when a heart murmur was heard. A tele-echocardiogram was done and critical pulmonary stenosis was discovered. Matthew required administration of the life saving medication, prostaglandin, and he was transported to Children's Memorial Hospital where his severely narrowed pulmonary valve was opened surgically. Matthew is now a normal 15-year-old boy with no symptoms of heart disease. Had telemedicine not been available, Matthew may have died as a newborn infant due to insufficient blood flow to his lungs.

Tele-echocardiography also enables the paediatric cardiologist to triage patients for different types of inpatient or outpatient care depending on the cardiac abnormality. In another case, a pair of twins was born to a mother at an outreach hospital. One twin was normal, but the other twin was a 'blue baby". Tele-echocardiography demonstrated that this baby had abnormal return of the venous blood from his lungs to the heart. Instead of returning to the left side of the heart the pulmonary venous flow returned to the right side of his heart, causing him to have abnormally low oxygen levels in his blood. Because this baby was very small, an immediate operation would have been very risky.

Using tele-echocardiography, the paediatric cardiologist determined that it was safe for this baby to stay in the ICU at the outreach hospital so that he could feed and grow bigger. When the baby was the appropriate weight, he was transferred elec-

#### COVER STORY: E-HEALTH - NEW HORIZONS FOR CARDIOLOGY

tively to Children's Memorial Hospital for repair of his anomalous pulmonary venous return. This management decision was also tremendously advantageous for the baby twins and their parents. Both babies remained in the same nursery and the parents were able to bond with both of them. Had one twin been transferred too early, the parents would have been required to split their time between two hospitals. Due to transportation difficulties, the parents would have had difficulty bonding with the twin with heart disease.

Finally, tele-echocardiography is very effective in defining cases of mild heart disease, which can be very easily managed in an outpatient setting. For instance, if a small hole between the upper or lower chambers

of the heart is found, the baby may be discharged with the mother and scheduled for routine follow up in an outpatient paediatric cardiology clinic. Prior to the advent of telecardiology, these babies may have been unnecessarily transported to the hub hospital for diagnosis or their discharge may have been delayed while waiting for an echocardiogram to be interpreted.

#### **Conclusions**

In summary, tele-echocardiography is a life-saving technology for infants with congenital heart disease. With a modicum of outreach sonographer training and real time interaction between the sonographer and the hub hospital paediatric cardi-

ologist, congenital heart disease can be diagnosed or ruled out. Time to diagnosis is decreased, improving the infant's chances of survival if heart disease is present, and expeditiously allaying parental anxiety if the heart is normal. Unnecessary costly transports and prolonged hospital stays are avoided. Since the distance between hub and spoke hospitals is irrelevant, telemedicine technology may also be an important solution to the diagnosis of congenital heart disease in remote parts of the globe without access to paediatric cardiology expertise. Thus, using this simple technology, outcomes for patients with congenital heart disease can be significantly improved not only locally but also throughout the world.

#### MAKING AN E-HEALTH INVESTMENT

#### High Potential Opportunity and Managerial Challenge

The increase in demand for health services tends more and more often to outstrip the increase in supply. Ageing populations, increasing incidence of chronic diseases, and improvements in medical knowledge and technological equipment are the main demand drivers across the EU. The financial and real resources available for meeting this increase in demand are limited. As a result of this worsening mismatch, the generic investment challenge is to improve the performance and capacity of the supply side in order to meet some of the growth in demand.



Alexander Dobrev (see left) (empirica)

Karl A. Stroetmann

Tom Jones (TanJent Consulting)

The European e-health IMPACT (2006, www.e-health-impact.eu) and EHR IM-PACT studies (2008, www.ehr-impact.eu) showed that effective e-health solutions can substantially contribute to improvements in quality, access and efficiency of healthcare, thus increasing the capacity of the supply side.

#### How to Invest in E-health

The recently completed Financing e-health Study (2008, www.financing-e-health.eu) provided a generic guide for potential e-health investors to support them in the decision-making process. The guide, addressing decision makers and managers, sheds light on, and draws the connection to, the overall decision taking and change management processes that are part of e-health investment.

The main lesson regarding the models to adopt is to integrate the e-health investment decisions into the healthcare strategy of the organisation. e-health can deliver, but it has to become part of the general resource mix considered in addressing healthcare needs. Then, e-health invest-

ments are considered alongside more conventional investments and the ones with the best value for money can be selected. The financing model for the investment should only be considered after the economic analysis is being performed. The approach is illustrated in figure 1, page 23. Too often, investments are driven by affordability considerations and not by a comparison between investment and the economic value of its impact.

#### The Process of Economic and Financing Decisions

Common difficulties in e-health investments reflect the differences between ehealth and conventional ICT investment. e-health focuses on changes in the way healthcare is delivered, which is a demanding endeavour. In e-health investment, ICT serves only as an enabler, not as an end. In this context, the main obstacles to success include:

- Unrealistic timescales;
- Underestimated risks;
- Inherent procurement difficulties, and
- A common misperception of the nature of most valuable benefits of ehealth.

#### **Timescales for E-health**

Project management for some e-health projects focuses mainly on deploying and managing the resources during the design, development and implementation stages, and possibly the initial stages of operation. This timescale can be too short for sustainable e-health investment, as shown in the chart below. It may fit an ICT project, but seldom provides the time required for the activities needed to realise net benefits: typically, about four years on average and at least eight years for EHRs. The appropriate timescales extend well beyond the business and financial planning of most healthcare provider organisations and can present financing challenges for e-health.

Instead, the e-health investment lifecycle should be set according to the time needed to realise the required net benefit, the ultimate objective. This will enable the management and productive utilisation of all the reallocated resources, as part of the change lifecycle.

#### **Managing Risks**

Like all investments, as complexity and scale increase, so do the scope, probabilities and costs of risk. Plans for e-health investment seldom evaluate the potential of risk realistically. The result is no recognition of risks as costs, no mitigation and no respective financial provision. This in turn leads to understated costs and overstated benefits, which is not a good foundation for e-health investment.

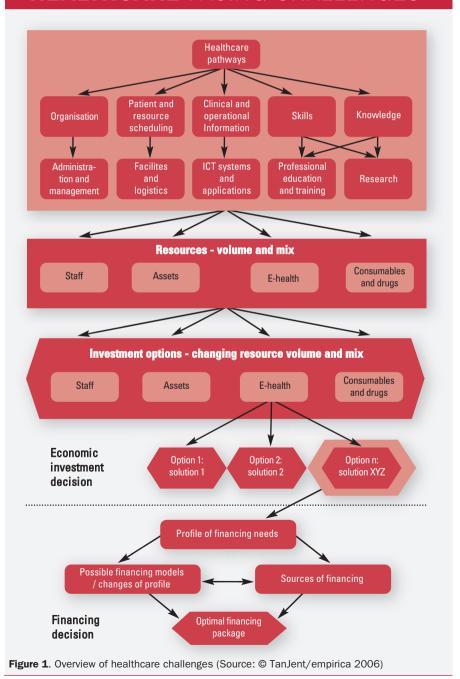
For example, engagement with users and other stakeholders is a high-risk activ-

ity. Where it is not successful, the effect can inhibit e-health activities for many years. Where it is successful, e-health investors tend to apologise for the extended timescales, understating the significant reduction in risk by pursuing effective collaboration and engagement, especially with healthcare professionals.

#### **Procurement**

Another concern is that there is still a mismatch between supply and demand for e-Health systems and tools. Experts consulted in the Financing E-health Study reported of repeated occasions in which ICT suppliers were not in the position to

#### **HEALTHCARE FACING CHALLENGES**



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supply the solutions needed for benefit realisation, leaving investors with the task to develop rather than procure. At the same time, requirements are not always set effectively by procurers, something that can make the lives of ICT vendors more difficult.

#### Garnering Added Value from E-health

The challenge is to ensure that the total investment matches an appropriate total economic benefit. It is important to treat ehealth investment in the same way as other new investments in healthcare, such as new drugs and surgical techniques. It should not be a means of saving money and improving overall cash flow, but an investment in better healthcare.

Large proportions of economic benefits from e-health are from quality, including patient safety, and time improvements. ehealth is usually a net investment, with a negative financial return, so financial benefits must be realistic in their value and their timing. Sustainable e-health investment requires that all decision takers and financial stakeholders be clear about the distinction between economic benefits and financial savings.

The task is to identify, define and describe all the benefits needed from better information for each strategic initiative. There are several examples, such as informing patients better, improving patient safety and timeliness, streamlining healthcare, improving clinical effectiveness by sharing patient information with other healthcare professionals that form the multidisciplinary team providing patient care, and modernising healthcare: all quality goals. Some citizens, such as those in remote locations, may need improved access to hospital and other specialist health services. Improving efficiency by saving time and cutting waste may be a priority.

#### Impact of E-health on Hospital Management

The critical requirement for leaders, executives and e-health stakeholders is to be able to deal with e-health investment as an in-

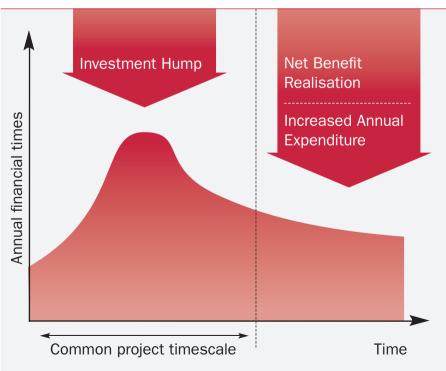
tegrated part of all healthcare investment. Finance executives and managers have a more specific role. First, they need to understand the value and impact of e-health, so they can extend and develop financial planning to deal with e-health investment timescales. Second, they need to extend their financial management skills to be able to develop ways to invest in better value.

"Some citizens, such as those in remote locations, may need improved access to hospital and other specialist health services."

This expands the principle of organisational change from healthcare professionals who use the e-health investment directly, to the whole organisation. It is just as uncomfortable for executives as it is for healthcare professionals. As healthcare professionals use new information to improve quality, access and efficiency, executives are confronted with new clinical, working, and information exchange practices: they have a different organisation to run.

#### **Conclusions**

E-health is slowly becoming a must have in modern healthcare. Expectations and resource constraints call for a high potential response, and e-health seems to be part of it. This seems to be common wisdom, but begs the question why e-health investments are not always successful in proving their potential. The answer is to some extent conveyed in this article, which is based on extensive research for the European Commission in the Financing e-health Study. More needs to be invested in acquiring appropriate knowledge and experience with e-health in order to master the managerial challenges associated with realising its potential.



**Figure. 2** An illustration of the financing needs curve of e-health investments Source: © empirica/TanJent 2006



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#### **INTERVIEWEE**

## Prof. Valentin E. Sinitsyn Chief Department of Radiology Federal Centre of Medicine and Rehabilitation Moscow, Russia vsini@mail.ru

## INTERVIEW WITH PROF. VALENTIN SINITSYN

Co-founder of the European Society of Cardiac Radiology Shares his Insights into the Need for Collaboration Between Radiologists & Cardiologists

Born in Elizovo, on the Kamchatka Peninsula in Russia on 14 November 1961, Prof. Valentin Sinitsyn began medical school at the Sechenov 1st Moscow Medical Institute in 1978, and graduated in 1984. From 1984 to 1988 he worked as a resident and fellow in the Diagnostic Radiology Department of USSR Cardiology Research Centre. In 1988 he was promoted to researcher and later to senior and leading researcher in the radiology department. He obtained his first doctoral thesis from the cardiology centre in 1989 (MD) and second (MD, PhD) in 1995. In 1994 he became professor of radiology. Today his main job is chief of the radiology department in the Federal Centre of Medicine and Rehabilitation. He has maintained a strong interest in cardiac imaging and serves as the Vice-President of the European Society of Cardiac Radiology (ESCR), which he co-founded.

#### **Professional Highlights**

#### **Memberships and Affiliations**

- Member of Congress Committee of the European Society of Radiology (ESR)
- Member of Executive Committee of Russian Association of Radiologists
- Vice-President of the European Society of Cardiovascular Radiology (ESCR)
- Member of International Society for Strategic Studies in Radiology (ISSSR)
- Member of European Society of Magnetic Resonance in Medicine and Biology (ESMRMB) (current position – member of External Relations Committee)
- Member of Radiological Society of North America (RSNA)

#### Publications:

- Author and co-author of more than 110 publications (cited in PubMed) covering subjects on cardiovascular radiology, magnetic resonance, general radiology, contrast media, internet and computer applications.
- Author and co-author of eight books published in 1997 2007 (Russian language) on "Radiology and Internet Applications in Radiology", co-author of a chapter in the book "Cardiac Radiology" (Springer, 2004, 2nd ed. 2008), editor of Russian versions of two international textbooks on MRI and CT.

#### **Teaching activities:**

Teacher and head of the radiology course at the Moscow State University

Invited speaker at multiple national and international congresses: ECR 1999 - 2008, ESMRMB 2003, 2004, 2006, 2008, ESCR 2000 - 2008, ISSSR 1997 - 2009, ICR 2004

#### How did you get started in your career?

In 1984, I was lucky enough to get an initial training in radiology at the Cardiology Research Centre in Moscow, which was headed by Russia's most accomplished cardiologist, academician Eugeny Chazov. For 24 years, I worked in the Cardiology Research Centre as lead researcher and radiologist.

In 2008, I was promoted to head of the imaging department in the Federal Centre of Medicine and Rehabilitation. It was a real challenge, as the volume and complexity of my work increased tremendously.

#### Please describe the institute where you work.

Today, I work in a modern, multi-profile hospital of 450 beds, which specialises in abdominal surgery, oncology, neurology and neurosurgery, cardiology, traumatology and sports medicine, gynaecology and urology, radiation oncology – and this is not even a full list.

Our specialists perform, annually, more than 9,000 surgical operations. Besides that, the hospital provides emergency care around the clock. Because of such multifaceted activity, demands made on the imaging department are quite high. The staff in our radiology department includes 45 radiologists and radiographers. It is equipped with three MDCT systems, four MR imagers, gamma camera and digital x-ray equipment, including a mammography service. For cardiac imaging in our department, we use 1.5T MRI (Avanto, Siemens) and VCT Discovery HD 750 (GE).

#### How did you come to be interested in cardiac imaging?

We work in all major fields of radiology, but cardiovascular diagnostics remains my favourite. This love of cardiac imaging began many years ago. In 1984, my hospital (at that time, the Cardiology Research Centre) acquired an MR imager- the first in the USSR. At the end of 1986, we acquired our first MR images of the heart. At this time, MR was a new area of imaging, and I was fascinated by the possibilities of this modality in cardiovascular diagnostics: one can do an assessment of heart anatomy and function, blood flow, myocardial viability and perfusion with one single modality. I still remember my first case of apical hypertrophic cardiomyopathy, detected by cardiac MRI in a patient with an unknown diagnosis.

My colleagues were initially skeptical about making such a rare diagnosis with an unknown diagnostic modality, but pretty quickly they changed their minds and started to refer more and more patients with difficult diagnoses. Later, we got our hands on EBCT and started to perform coronary CTA, CT-ventriculography and studies of myocardial perfusion. After EBCT we switched to MDCT.

#### How did the creation of the European Society of Cardiac Radiology come about?

In 1999, a group of radiologists, including myself, founded the European Society of Cardiac Radiology (ESCR). It has grown rapidly since its foundation in 1999 and has hosted successful meetings in several European cities since the first annual scientific meeting in Berlin in 2002. The rapid growth and popularity of the society reflects the general success of cardiac radiology. Being Vice-President of the ESCR is a great professional honour for me.

#### What innovations will be made possible by cardiac CT and MR?

Cardiac images are getting better and better. We hope that the image quality of

coronary CTA will be high enough to completely replace diagnostic invasive cardiac catheterisation in the very near future. Besides that, many research groups are trying to use MDCT for simultaneous analysis of coronary anatomy and myocardial perfusion.

For many years, MRI was definitely superior to CT in cardiac studies, except for coronary imaging. Thanks to technological advances, cardiac CT is entering the myocardial imaging area, where until recently, nuclear medicine and MRI dominated. Even cardiac valves can be successfully imaged today with MDCT. The progress of cardiac MRI also is speeding up. Therefore, the situation between the clinical usage of CT and MRI is increasingly competitive.

### Are specific management qualifications required to climb the career ladder?

Formally, in my country, one does not need special management qualifications in order to eventually be promoted to chief of a department. However, personal characteristics, experience in teamwork and working in a multidisciplinary setting, achievements in academia and research and in a variety of clinically different projects as well as poassing on knowledge and expertise through mentoring, matter a lot for any senior appointment.

## What are the most enjoyable aspects of your professional life, and which are the most challenging?

One of the most enjoyable aspects of my profession is the education of young doctors. My department is a base for teaching radiology to medical students from the medical faculty of the Moscow State University and postgraduates from different institutions.

Since the mid '80s, we presented our papers and abstracts at different international meetings, read articles and books from our colleagues from Europe and the U.S. and, step-by-step I became acquainted with those radiologists performing noninvasive

cardiac imaging. Later, I got invitations to present lectures on cardiac imaging. One of the challenging aspects of my job is that running a radiology department takes a lot of my time. Honestly speaking, I didn't expect that it would be so complicated. Nevertheless, I still find time for clinical work and to organise and direct research activities in my department.

#### How strong is the need for good leadership in cardiac radiology?

I believe that today, a radiologist must be a real leader and expert in his field. We are not just interpreting cardiac images. A good cardiac radiologist contributes a lot to a patient's further management, helping to define further strategy and diagnostic work-up and treatment. Good cooperation between radiologists and cardiologists is crucial for achieving best results in cardiac imaging.

#### How comparable is the level of available sophisticated cardiac imaging technology in Russia to Western Europe?

The backbone of cardiac imaging is still formed by echocardiography and cardiac catheterisation. We have some local guidelines for usage of MDCT and MRI in cardiac patients written with my participation. At the end of the last century just a few academic centres in Russia performed cardiac imaging with EBCT, 4-row MDCT or high-field MRI.

Today the popularity of cardiac radiology is tremendous. During the last five to six years, Russian hospitals acquired hundreds of MDCT and MRI systems. Russian radiologists – like their western colleagues – have the latest generation CT and MR scanners. Information about the outstanding diagnostic capabilities of modern diagnostic equipment have spread all over our community and many radiologists are eager to master new fields of imaging like coronary CTA or cardiac MR. In conclusion, it looks like cardiac imaging, worldwide in general and in Russia in particular, is evolving and gaining in popularity.

## DEVELOPMENTS IN STRUCTURAL HEART DISEASE INTERVENTIONS

#### How Progress is Changing Practice for Interventional Specialists







**AUTHORS** 

Dr. Jennifer Franke (top left)
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Interventional treatments of structural heart disease are evolving at a rapid pace and are now established routine in many centres worldwide. Some have even left the traditional interventional field of cardiology behind and have emerged from coronary catheterisation labs into specialised units for catheter-based therapy of structural heart diseases. The term "structural heart disease interventions" was primarily established by Dr. Martin Leon at the Transcatheter Cardiovascular Therapeutics Conference (TCT) in 1999, when he was looking for an over-arching category to describe catheter-based treatment modalities of various types of non-vascular heart diseases at a time when many of these concepts were just on the horizon. Over the last ten years, this term has been generally accepted as a category of disease by the medical community. The following overview highlights the newest commercially available devices, as well as developing strategies to treat structural heart diseases percutaneously.

#### Catheter Closure of Congenital and Acquired Shunts

#### **PFO Closure**

A wide variety of percutaneous devices targeting congenital and acquired heart defects have recently become commercially available or are currently evaluated in clinical trials. In transcatheter closure of patent foramen ovales (PFO) for example, a trend can be seen towards defect-tailored devices and new designs or techniques which minimise the amount of foreign material left in the atria after implantation. Promising new concepts of PFO closure include the SeptRx<sup>TM</sup> device (Stout Medical Group, U.S.), which is positioned into the PFO pocket and is stabilised by two left atrial anchors that adapt to the tunnel length without significant alteration of the configuration of the septum primum (Majunke N et al. 2008) or the Coherex FlatStent<sup>TM</sup> PFO closure system (Coherex Medical, Inc., Salt Lake City, UT, U.S.) which consists of a light-weight, self-expanding, flat "stentlike" Nitinol lattice with integrated polyurethane foam designed to stimulate tissue growth inside the PFO tunnel.

The BioTREK<sup>TM</sup> (NMT Medical, Boston, MA, U.S.) is a fully bioabsorbable device. Its main component is a novel biosynthetic polymer named poly-4-hydroxybutyrate (P4HB) (Tepha, Inc., Lexington, MA, U.S.). As this device, which is currently in pre-clinical studies, is eventually replaced with native tissue, late device-related complications may be avoided. Another concept is the HeartStitch<sup>TM</sup> (Sutura Inc., Fountain Valley, CA, U.S.) strategy, which is based on the SuperStitch vascular suturing system designed for vascular stitching in general surgery (Ruiz CE et al. 2008).

One of the most recent techniques for PFO closure under clinical investigation is the Nit-Occlud® PFO umbrella (Pfm medical mepro, Nonnweiler-Otzenhausen, Germany) which is a double-disc Nitinol device incorporating a synthetic patch on the left and right atrial side in order to achieve a high acute closure rate.

As the discussion on the potential pathological importance of PFO and the best possible therapy for secondary stroke prevention is still on, these new concepts for PFO closure will hopefully lead to further decrease of acute and late device-related complications. Safety and long-term reliability of novel devices are especially important when PFO closure is discussed in migraine patients or divers.

#### **ASD Closure**

Percutaneous techniques for most secundum atrial septal defects (ASD) have largely replaced surgical closure. New devices commercially available are the partially bioabsorbable BioSTAR® occluder (NMT Medical Inc. Boston, MA, U.S.) and the Occlutech® ASD device (Occlutech, Jena, Germany). Despite this era of new technologies, conventional surgery currently remains the primary treatment modality for large defects (> 40mm), non-secundum defects and for those atrial septal defects in which the septal rim is insufficient.

#### **VSD Closure**

Ever since the very first interventional approach to ventricular septal defect (VSD) closure described in 1988 (Lock et al. 1988), various catheter-based techniques have been proposed for this purpose such as the Sideris buttoned device, the Rashkind device, Gianturci coils, the Clamshell device, the CardioSEAL and CardioSEAL/STARflex device, the Amplatzer occluder family and Nit-Occlud coils. Compared to transcatheter atrial septal defect or patent foramen ovale closure, interventional closure of ventricular septal defect is considered rather complex while it requires both venous and arterial access to establish an arteriovenous wire loop. Efficacy of percutaneous closure of muscular ventricular septal



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defects has been reported for over a decade. Moreover, since the introduction of the Amplatzer Membranous ventricular septal defect occluder (AGA Medical, Golden Valley, MN, U.S.), perimembranous defects which have a higher incidence, have become more amenable to transcatheter closure techniques (Hijazi ZM 2003). However, there is an ongoing discussion as to whether coils may be an advantage due to the presumably reduced risk of AV block.

In post-myocardial infarction VSDs, interventional closure has shown to be feasible as well. However, despite gaining expertise and novel devices, due to the often atypical location of the defect, deficient and irregular rims and the presence of multiple defects, transcatheter treatment remains a major challenge for today's interventionalists.

#### Closure of Patent Ductus Arteriosus

The ductal anatomy is known to be quite variable with the most common phenotype being a conical duct with a large aortic ampulla which narrows at the pulmonary artery end. Due to this variability, a number of different concepts of closure have been developed, e.g. Cook PDA coils (Cook Inc., Bloomington, IN, U.S.) for small PDA or a specific Nitinol duct occlusion devices like the Amplatzer® Duct Occluder (AGA Medical, Golden Valley, MN, U.S.) for larger PDAs.

#### Valve Repair/Implantation

For many years, catheter-based treatment of valvular heart disease was limited to balloon valvuloplasty. After having performed the first percutaneous valvuloplasty of a calcified, stenotic aortic valve in 1985, Dr. Alain Cribier went on to replace the first aortic valve mounted on a balloon-expandable stent percutaneously in 2002. Since then, percutaneous aortic valve replacement is performed in an increasing number of centres worldwide and has become an alternative therapeutic option to surgical valve replacement in selected elderly patients who have an unacceptable high risk of surgery.

Concerning patients with significant mitral regurgitation, surgical valve repair continues to be the primary treatment strategy. However in the light of rapid developments in interventional treatment, percutaneous mitral valve repair has likewise become an interesting alternative therapy. Multiple percutaneous technologies are currently being evaluated in preclinical and clinical settings. Percutaneous mitral annular remodelling strategies include indirect mitral annuloplasty approaches such as coronary sinus annuloplasty (Edwards MONARC<sup>TM</sup> (Edwards Lifescience Corp., Irvine, California, U.S.), CARILLONTM Mitral Contour System (Cardiac Dimensions, Kirkland, Wisconsin, U.S.), Percutaneous Transvenous Mitral Annuloplasty system (PTMA®) (Viacor, Inc., Wilmington, Massachussetts, U.S.) and Mitral valve cerclage annuloplasty (MVCA) (NIH, Rockville, MD, U.S.), and other indirect annulolasty approaches such as the Ample PS3<sup>TM</sup> (Percutaneous Septal Shortening System) (Ample Medical Inc., Foster City, California, U.S.).

"In post-myocardial infarction VSDs, interventional closure has shown to be feasible."

In addition, direct mitral annuloplasty approaches e.g., QuantumCor (Quantum-Cor, Inc., Lake Forest, California, U.S.) via direct percutaneous trans-atrial annulus remodeling or the Mitralign<sup>TM</sup> (Miralign, Tewksbury, Massachusetts, U.S.) and the AccuCinch<sup>TM</sup> (Guided Delivery Systems, Santa Clara, California, U.S.) device via direct percutaneous trans-ventricular annulus remodeling are currently under investigation. Other annulopasty concepts consist of mitral annular plication, chamber remodelling approaches and hybrid procedures. Percutaneous solutions, which directly target the mitral leaflets like the MitraClip® System (Evalve, Inc., Menlo Park, California, U.S.) mimic the edge-toedge surgical technique introduced by Alfieri successfully with encouraging midterm results (Feldman et al. 2009).

#### Closure of Paravalvular Leaks

After Hourihdan reported successful interventional closure of paravalvular leaks in three patients in 1992 (Hourihan et al. 1992) a number of other cases on this topic have been published reporting best results in patients with small diameter non-progressive leaks in aortic position. Suitable devices for paravalvular leak closure are the Amplatzer Muscular ventricular septal defect occluder (AGA Medical, Golden Valley, MN, U.S.) and the Amplatzer PDA occluder.

For larger defects around the mitral valve implantation of the Amplatzer ASD occluder is feasible. Quite recently, the Amplatzer® Vascular Plug III (AGA Medical, Golden Valley, MN, U.S.) (figure 3) which is oval shaped and has smaller rims for better apposition in even in high flow vessels, has been introduced. In comparison to other devices of the Amplatzer vascular plug family, first experiences with this dedicated device show better suitability for closure of paravalvular leaks.

#### Left Atrial Appendage Closure

Occlusion of the left atrial appendage in patients with non-rheumatic atrial fibrillation was first attempted by cardiac surgeons during open heart surgery (Blackshear JL et al. 1996; Johnson WD et al. 2000). The first two interventional approaches specifically developed for occlusion of the left atrial appendage were the PLAATO<sup>TM</sup> device (eV3, Inc., Plymouth, MA, U.S. - not available anymore) and the Watchman® implant (Atritech, Inc., Minneapolis, MN, U.S.).

Data from the PROTECT-AF randomised trial have just been published which showed non-inferiority of the Watchman® implant compared to warfarin therapy for stroke prophylaxis (Holmes DR et al. 2009) and therefore pointing out the great potential of percutaneous occlusion of the left atrial appendage as an alternative to long-term anticoagulation. Next to the Amplatzer® septal occluder (AGA Medical Corporation, Golden Valley, MN, U.S.), which was not

originally intended for occlusion of the left atrial appendage but has been reported with acceptable results (Meier B et al. 2003), the Amplatzer® cardiac plug (AGA Medical, Golden Valley, MN, U.S.), specifically developed for atrial appendage occlusion, is now available within a European registry.

#### **Endless List of Techniques**

The list of developing techniques seems endless and demonstrates that this medical field is expanding at a stunning pace. Some interventional techniques like closure of atrial septal defect and patent foramen ovale have already proven to be effective. Low complication rates of many catheter-based therapies of congenital shunts and satisfactory results in long-term follow-up have led to a higher acceptance from physicians and patients alike, and consequently have led to the replacement of surgery as the standard therapeutic approach.

One must acknowledge that the prevalence of most structural heart diseases is comparably low. Therefore, a major growth in numbers of interventional procedures as with interventional therapy of coronary heart disease cannot be expected. Critics may as well claim that some novel percutaneous approaches may potentially be less efficacious than present surgical standards.

#### **Need for Less Invasive Solutions**

However, it is unquestionable that there is an enormous need for less invasive catheter-based solutions as alternative strategy, particularly in the treatment of patients at high surgical risk. Moreover, due to the complex anatomy and broad pathophysiological spectrum of some structural heart diseases, it will likely be necessary to combine different therapeutic strategies in order to achieve satisfactory results - as is still the case with conventional surgery today.

Discussions concerning the balance between advances in catheter-based technology and the cost-effectiveness of patient treatment have concurrently arisen. Percutaneous aortic valve replacement for example, raises the costs of treatment compared to traditional surgical valve replacement. Looking at the present target patient cohort, who perhaps wouldn't have been considered for surgery and therefore would have been treated by medical therapy alone, the costs are increased significantly.

Glancing beyond this discussion, more dedicated fellowship programmes need to be developed to provide hands-on training as well as accessible research platforms for those interested in turning empirical clinical know-how of structural heart diseases into pre-clinical research and subsequently transforming successful technologies into feasible interventional solutions of the near future.

#### DIASTOLIC DYSFUNCTION AND DIASTOLIC HEART FAILURE

Part One: Pathophysiology



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Diastolic dysfunction represents a mechanical malfunction of the relaxation of the left ventricular chamber primarily diagnosed by two-dimensional transthoracic echocardiography and in most cases, has no immediate clinical relevance. The abnormal relaxation is usually separated in different degrees based on the severity of

reduction in passive compliance and active myocardial relaxation. Diastolic heart failure, in contrast, is a clinical diagnosis in patients with signs and symptoms of heart failure but with preserved left ventricular function and normal ejection fraction, and is often seen in patients with long-standing history of hypertension or infiltrative cardiac diseases. The question of whether diastolic dysfunction will ultimately lead to diastolic heart failure is critically reviewed based on data from the literature. Treatment recommendations for diastolic heart failure are primarily targeted at risk reduction and symptom relief. Currently, few data have been reported on diastolic dysfunction and its progression to systolic heart failure.

#### Introduction

Even though often interchangeably used in a clinical setting, there is a distinction between diastolic dysfunction and diastolic heart failure. A PubMed literature search revealed a total of 1,478 articles using the search terms diastolic heart failure and review. In contrast, few randomised controlled trials are available on diastolic heart failure alone. Controversy remains regarding the optimal therapy for patients with either diastolic dysfunction or diastolic heart failure. An important question is whether diastolic dysfunction does indeed lead to diastolic heart failure and how this progression occurs. Moreover, it is unclear whether diastolic dysfunction consequently results in both diastolic and subsequently, systolic heart failure.

In daily routine, heart failure oftentimes is separated into systolic and diastolic failure based on preservation of left ventricular ejection fraction. The terms "heart failure with preserved left ventricular function" or "heart failure with normal ejection fraction" are used to emphasise that the etiology of the pathophysiology for this group

of patients may go beyond diastolic dysfunction alone. Heart failure in general and diastolic heart failure in particular causes a significant financial burden and increasing consumption of healthcare resources, especially among the elderly population (i.e., for patients 65 years of age or older). The present article will review the current knowledge of diastolic dysfunction and its progression to diastolic heart failure.

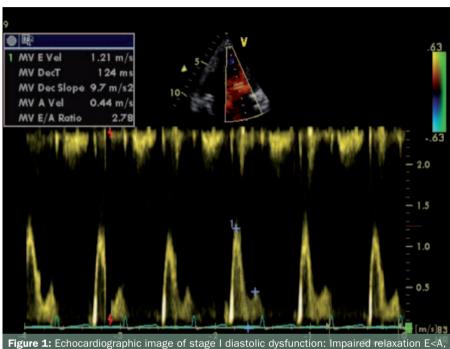


Diastolic dysfunction is a mechanical abnormality brought on by a breakdown in the passive (compliance) and active (myocardial relaxation) intrinsic properties of the ventricle during diastole. Myocardial hypertrophy (e.g. left ventricular hypertrophy secondary to hypertension) and myocardial ischaemia have been shown to impair the energy-dependent process of myocardial relaxation. The increased afterload in patients with aortic stenosis or hypertension can also inhibit myocardial relaxation by reducing the ability of the left ventricle to contract to small end-systolic volume, and hence limit the ensuing elastic recoil's ability to enhance myocardial relaxation.

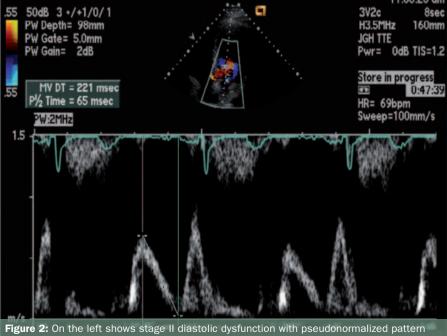
Also, diastolic dysfunction can be secondary to pathological states that adversely affect passive compliance during diastole, such as increases in myocardial wall thickness observed in concentric hypertrophy as a result of longstanding hypertension, or in myocardial fibrosis in patients with infiltrative pathology.

#### The Role of Echocardiography in the Assessment of **Diastolic Function**

Diastolic function can be evaluated noninvasively using two-dimensional transthoracic echocardiography. The evaluation of left ventricular diastolic function should be an essential part of any echocardiography examination. The three phases of diastole consist of a period of isovolumic relaxation time (IVRT) followed by early rapid diastolic filling period (E), a plateau and finally a late filling due to the atrial contraction or atrial kick (A). These can



E/A ratio <1.0, DT>200< IVRT>90.



where E/A reverses with valsalva maneuver.

be evaluated by using the pulse wave (PW) Doppler of the mitral valve and pulmonary veins. The left ventricular filling pattern obtained will therefore indirectly reflect the left ventricular filling pressures.

A complete left ventricular diastolic assessment should include assessment of the IVRT, peak E velocity, peak A velocity, E/A ratio, deceleration time (DT), and A duration, which are obtained from the transmitral inflow velocities. Pulmonary vein (PV) flow velocities are then measured, which include four components: two systolic velocities (PVs1) and (PVs2), diastolic velocity (PVd), and atrial flow reversal (PVa). Based on the echocardio-

graphic parameters, diastolic dysfunction has been divided in three different grades of severity of ventricular compliance, relaxation rate, and filling pressures.

- Stage one is the mildest form of diastolic dysfunction with delayed relaxation defined by an early filling to late or atrial filling (E/A) ratio less than 1, prolonged IVRT and prolonged DT. The systolic to diastolic pulmonary venous (S/D) ratio is greater than 1 (see figure 1, p. 32)
- Stage two is marked by a moderate level of dysfunction and defined by E/A of greater than 1 and/or greater than 2
- with S/D less than 1, and is often called pseudonormalisation (with a normal diastolic filling pattern), caused by elevated left atrial pressures. This can be unmasked by reducing preload, for example by use of the Valsalva maneuver or application of sublingual nitroglycerine (see figure 2, p. 32).
- Stage three is marked by a restrictive filling pattern and signifies severe diastolic dysfunction, i.e., decreased compliance and marked increase in left atrial pressure. The E/A is greater than 2, IVRT and DT are short, S/D is less than 1 (see figure 3). The mitral A duration is shorter than the PVa duration.

Mitral annular velocity by tissue Doppler imaging also has been used to assess diastolic function. This referred to as E'. The E m (mitral)/ E' (annular) ratio has been found to correlate well with increased pulmonary capillary wedge pressure (PCWP). The E/E' ratio is normally less than 8. The E' is shown to be low in restrictive stage less than 8. A ratio of greater than 15 indicates elevated PCWP (see figure 4). Although rarely performed for evaluation of diastolic dysfunction alone, the most accurate invasive diagnostic technique is cardiac catheterisation with direct measurements of left ventricular end-diastolic pressure. Parameters of chamber stiffness are correlated with changes in pressure to changes in chamber volume.

# Figure 3: Stage III diastolic dysfunction: Restrictive stage of diastolic dysfunction: E/A ratio >2.0, DT <160, IVRT <70.

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**Figure 4:** Doppler Tissue Imaging (DTI): E' is < 7 indicating restrictive filling pattern. The E/E' is >15 suggesting elevated PCWP.

#### Left Ventricular Diastolic Dysfunction

In its simplest form, left ventricular diastolic dysfunction is defined as impairment in the capacity of the left ventricle to accept blood without a compensatory increase in left atrial pressure. Patients with left ventricular diastolic dysfunction tend to have elevated left ventricular diastolic pressure in the presence of normal or even reduced left ventricular volume, as the pressure-volume curve in these patients is shifted upwards. Over the years, a variety of co-morbid conditions have been associated with development of left ventricular diastolic dysfunction, such as myocardial

scarring, transmural myocardial infarction, chronic constrictive pericarditis, chronic coronary artery disease, dilated cardiomyopathy, hypertrophic cardiomyopathy, diabetic cardiomyopathy, hypertension, aortic stenosis as well as normal aging.

The underlying connection in the possible etiologies of left ventricular diastolic dysfunction is their ability to hinder one or both of the intrinsic diastolic properties of compliance or relaxation. Pathological states such as fibrosis and concentric hypertrophy can reduce compliance of the myocardium by increasing passive ventricular stiffness, thereby affecting the passive property of compliance in diastole. Ischaemia and disease processes leading to increased afterload affect diastole by impairment of the active rate of relaxation.

#### Left Ventricular Diastolic Dysfunction and Heart Failure

The prevalence as well as overall significance of diastolic heart failure has become distinctly apparent. Diastolic heart failure was originally reported in 1937 when Fishberg referred to it as "hypodiastolic failure", a

form of cardiac insufficiency secondary to inadequate filling of the left ventricle during diastole. A half a century later, Kessler became the first to discuss the clinical syndrome of diastolic heart failure. Over the years, a number of landmark publications have guided our current understanding for diagnosing diastolic heart failure. Recognising the difficulty of non-invasive assessment of the LV diastolic function, in 2000, Vasan and Levy proposed a classification scheme for diagnosis of diastolic heart failure in the hope of reducing the difficulty for diagnosis of this rather prevalent pathology.

According to the degree of diagnostic certainty, patients were partitioned into possible, probable, or definite diastolic heart failure. While keeping the need for evidence of heart failure for all categories, the diagnosis of probable or definite diastolic heart failure required evidence of normal left ventricular systolic function within three days of an initial heart failure event. Most importantly it was argued that "evidence of abnormal LV relaxation, filling, diastolic distensibility, or diastolic stiffness" is required for a definite diagnosis of diastolic heart failure. More recently, Zile and colleagues published sever-

al prospective studies concluding that the diagnosis of diastolic heart failure does not require objective recording of left ventricular diastolic dysfunction but only documentation of preserved systolic function. In two separate studies using both Doppler echocardiography and cardiac catheterisation, the authors observed a statistically significant percentage of patients with clinical diagnosis of heart failure and normal ejection fraction (EF >45 percent) suffering from abnormalities in active relaxation or passive compliance.

The degree of involvement that left ventricular diastolic dysfunction plays in preserved ejection fraction heart failure is debatable and has been the major argument made by those that believe diastolic heart failure is the correct diagnosis for patients with heart failure and normal ejection fraction, given that these patients do not suffer from significant valvular, pericardial or pulmonary disease. Left ventricular diastolic dysfunction has also been found to be present in patients with heart failure and reduced ejection fraction, a form of heart failure that was originally believed to be mainly secondary to a systolic dysfunction pathophysiology.

#### **BOOKS IN REVIEW**



#### Heart Failure: Device Management

February 2010 Edited by Artur Feldman

When you're considering device therapy for a patient with heart failure, a new publication should provide an aid to practitioners, who can consult this concise reference for the latest information on who benefits most from which device. In clear, straightforward prose, heart failure expert Dr. Feldman addresses related topics such as:

- · Resynchronisation Therapy
- ICD
- Ultrafiltration
- Impulse Therapy
- Chronic Implantable Monitoring

- Bioimpedance
- · EECP, and more.

With chapters devoted to monitoring the patient on device therapy and the future of device therapy in heart failure, this book makes an important contribution to patient care.

#### **Highlights:**

Within the covers of 'Heart Failure', topics covered by the different chapters and authors include:

- Cardiac Resynchronisation Therapy
- Implantable Cardioverter-Defibrillator Therapy
- Chronic Implantable Monitoring
- Role of Cardiac Restraint Devices in the Treatment of Patients with Dilated Cardiomyopathy
- The Role of Right Heart Catherisation in Management of Patients with Heart Failure

- Impedance Cardiography
- The Use of Echocardiography in Evaluating the Heart Failure Patient and Response to Therapy
- · Revascularisation for Left Ventricular Dysfunction
- · Minimally Invasive Treatment of Mitral Valve Disease
- Percutaneous Mechanical Assist Devices

#### **About the Editor**

Dr. Feldman served as a post-doctoral fellow in physiology at the Johns Hopkins University School of Medicine. After completing his medical degree at the Louisiana State University School of Medicine, he returned to Johns Hopkins where he served as an intern, resident and cardiology fellow. After joining the faculty in 1985, he was named the Director of the Belfer Laboratory for Molecular Biology of Heart Failure and the Director of the Heart Failure Research Program at The Johns Hopkins University School of Medicine. In 2004 Dr. Feldman joined the faculty at the University of Pittsburgh School of Medicine as the Harry S. Tack Professor of Medicine, Chief of the Division of Cardiology, and Director of the Cardiovascular Institute of the UPMC Health System. He has published over 200 peer-reviewed articles.

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### MANAGING SURGE CAPACITY

### **Balancing Resource Utilisation**

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Worldwide, healthcare systems are struggling with higher costs and demands of becoming more cost-effective. Despite our efforts, diseases cannot be exterminated and treatments of curable diseases sometimes result in the manifestation of new ones. For instance, decreasing neonatal mortality has been replaced with diseases among aging population e.g. cancers, raising the need for new areas of competency, treatment alternatives and technologies. The latter is considered to be the highest cost increase for today and tomorrow's healthcare - a desirable improvement in healthcare quality, but at a cost, that has not been included in our economic calculations.

### **Swedish Healthcare Provides Model**

The Swedish healthcare system has seen dramatic changes during the last two decades. An increasing elderly population combined with improvements in medical technology and treatment facilities has led to a situation with ever-increasing demand on healthcare. In a healthcare system that is almost 100 percent funded by taxpayers, and since Sweden has some of the highest income taxes in the world, thus increasing taxation rates has not been a viable political option. Instead these challenges have been met by several different measures:

- A more "efficient" hospital system has been created, often using large manufacturing industries as a "blueprint";
- The length of stay (LOS) has been reduced dramatically for all patient

- groups and more diseases and conditions are treated on an outpatient basis or in day-care surgery; also
- Stockpiling of supplies has been replaced by systems of "same day delivery" (Carlsson 2007; OECD Health data 2008), and
- In the last 20 years, the number of hospital beds in Sweden has been reduced from around 100,000 to 26,000. Several emergency hospitals have closed or been converted to facilities dealing only with elective cases.

These changes have obvious implications for the hospital surge capacity in cases of major incidents or disasters – a fact that is rarely openly discussed. In disaster/armed conflict planning in the 1980's, it was assumed that 1/3 of all in-hospital patients in Sweden could be immediately discharged should there be an influx of trauma patients. Such an assumption would be completely unrealistic today! A major task for many consultants on call in Swedish emergency hospitals is to prioritise which patients must be discharged in order to make hospital beds accessible for newly admitted patients, a task sometimes referred to as "reverse triage".

### **100% Occupancy a Distant Goal**

From an economic point of view, the most efficient way of utilising given resources is a 100 percent occupancy at all given times. This can be achieved in an ideal and purely elective setting with much standardised care provided that no untoward events occur. In emergency care such a perfect balance between given resources and demand is much more difficult to achieve and maintain. In reality, certain key resources, e.g. ICU beds, are often over-utilised. However to have a preparedness that can deal with a sudden increase in demand for emergency care there must be a certain "reserve capacity" built into the system.

This is what all emergency hospitals use on an everyday basis dealing with trauma alerts, myocardial infarctions or other potentially life-threatening conditions. Thus, medical preparedness - even for everyday emergencies - carries a cost and has to compete with other priorities within the healthcare system. Preparedness to increase the capability of a hospital or a hospital system beyond the everyday influx of emergencies in order to deal with a major incident/disaster (surge capacity) will also draw resources. Perhaps there is positive aspect to the recent global terrorist actions and the on-going pandemic of influenza (A/H1N1) in that the resulting media coverage has highlighted the need for every hospital management to review their disaster plans.

### **Risk Assessment the Key**

The key question in attempting to increase surge capacity is which costs can be justified in a sector that is under constant financial constraint? Decisions must be made based on estimates of realistic predictions on which disasters we will see in the future (risk assessment). Climate changes and global warming are additional hazards that might completely change both risks of incidents as well as vulnerabilities within our societies. The complexity of these issues merits a multi-disciplinary approach, in which relevant hospital and pre-hospital preparedness must be assessed by experts on disaster medicine.

Financial constraints are obvious in the generic planning phase for a disaster, but often seem to evaporate in the aftermath of an actual event. The result is often costly actions with little or even counter-productive effects on the stricken society and population. It is time to realise that money spent on scientifically based generic plans on how to increase healthcare surge capacity is the way forward. It is time to get rid of the old myths regarding disasters!

### MATCHING TALENTS AND JOBS

Programmed to under-perform? This is how some healthcare managers may feel when they go home after a typical day at work, according to a recent white paper 'What Does Being in Over Your Head Look Like'. In reality, the average healthcare organisation creates leadership alignment (the right people in the right roles) approximately 55 percent of the time. Realistic expectations for leadership appointment should target 85 percent alignment, by using a structured approach to determining their future leaders. The difference of having the right leaders in place can show as much as a 75 percent increase in operational performance over time.

AUTHOR

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There are several common appointment mistakes that may lead to sub-optimal performance, where newly appointed healthcare leaders and managers whose talents are not best matched to a new role, can end up in over their heads.

The easiest way to describe the condition is where a department's complexity (degree of difficulty) exceeds the threshold at which a manager has higher odds of success (typically above a 50 percent rate). There are different levels of ability. For a 'C' level ability, this is virtually any management job, since their chances of success are at best just 40 percent (in the lowest complexity positions). The decision to appoint a 'C' level manager to high positions is justified only when challenges are easily managed, or if the manager has an exceptional ability to manage day-to-day operations.

How about 'B' level managers? As cited by Thomas J. DeLong and Vineeta Vija-yaraghavan in their 2003 'Harvard Business Review Article', 'Let's hear it for B players', managers at the 'B' level are solid, consistent performers. They are competent, experienced, consistent and loyal.

These managers make up the backbone of any organisation, and typically account for between 50 percent and 55 percent of executives. In our research, the bulk of healthcare IT managers are usually at the 'B' level. For 'B' level leadership talent, the ability to manage low and medium complexity tasks produces favourable results, respective.

tively, 75 percent and 60 percent of the time (see Figure 1). The only cases with low odds of success (and are 'in over their heads') is when they are appointed to complex assignments or departments, accompanied by a high degree of difficulty. It is here that the chances of success dip to 45 percent. This is not to say that they cannot be successful; it is just less likely. If a decision is made to appoint 'B' level IT managers to such a level of complexity, it is crucial for CIOs to ensure that they 'over achievers.

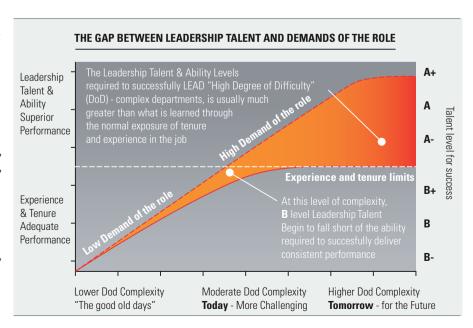
Other attributes of "B" level leaders are:

- They are talented but not usually as ambitious or driven;
- They are interested in advancement but not at all costs or a steep price;
- They define success differently (not purely financially or status motivated);
- While they may work hard, they prioritise "life-work" balance to work 50

- hours per week instead of 80 or more;
- They are usually excellent team players avoiding the spotlight of self promotion;
- They may have been "A" level performers at one time and have dialled back their career focus due to outside personal priorities or possibly "throttling" down to semi-retirement;
- They have longer tenures in organisations because they are less likely to leap from job to job to fast track or advance their careers, or
- They contain a significant amount of an organisation's intellectual capital due to their experience and tenure levels.

In such a light, there are seven typical appointment mistakes which organisations make:

1. Appointing a "B" level ability person to a high degree of difficulty management role based upon their tenure pe-





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According to the White Paper, the most common causes that create the environment where seemingly good people (but sub-optimised leaders) tend to get in over their heads include:

- Managers are appointed before they are truly ready - they are not quite experienced or mature enough
- Managers are appointed when their demonstrated leadership talent is deficient
- Managers are appointed to a department where the degree of difficulty exceed their ability to get good results
- Managers are appointed out of necessity or convenience

riod or technical competency (clinical expertise); the ability to lead others does not correlate with either. Odds of success = 45 percent.

2. Appointing a lower level "supervisor" into a manager position in a bottom quartile department out of convenience. They are usually unsuccessful because of their lack of manager experience. They tend to be part of the previous culture and are less likely to act on the low performers (or make

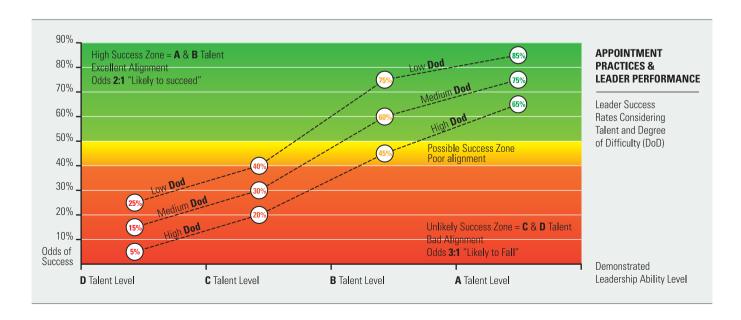
- tough decisions). Odds of success = < 20 percent.
- 3. Failure to recognise that a high degree of difficulty department in the bottom quartile will require a 'turnaround' specialist used to making tough decisions quickly, with responsibility to stakeholders outweighing personal interests. Most 'B' level managers do well in maintenance roles. Odds of success = < 20 percent.
- 4. Waiting too long to act and failing to set hard (measurable) performance targets and milestones for the first year. If new managers fail to immediately make heavy-lifting decisions (especially in terms of dealing with negative, disruptive, poor performers), turnarounds take longer, are usually more painful and have a lower overall success rate. Odds of success = < 20 percent.
- 5. Not taking due account of leadership talent or ability. Assigning a 'C' or 'D' level leader in any role has low odds of success: average 30 percent for a 'C' player and 15 percent for a 'D'.
- 6. Low acceptance rate of a new leader/manager by the staff because of an 'old school' mindset about the im-

- portance of prior tenure in a particular department. It can be extremely difficult for some people to handle this situation long enough to persevere. Odds of success = < 33 percent.
- 7. Competency Alignment: Sometimes, even the most talented leaders ('A' players) can be out of alignment technically, with regard to business models, culturally/behaviourally or in terms of pure maturity or experience. Odds of success = < 33 percent.

Numerous consultants promote the hiring of only 'A' players to leadership and/or total employee positions. If less than .01percent of healthcare organisations can achieve this level of human capital recruitment, hiring and appointment, how realistic is it as an aspiration? The last organisation that tried to create a culture of all 'A' players was Enron.

Another name for this business practice is 'Top Grading', where selection only screens for the best talents, while the performance management practices cut a percentage of the total employment base (GE is famous for cutting 10 percent of its bottom performers every year).

Such a philosophy will simply not work at healthcare organisations. In the final analysis, the healthcare business, like others, is a team sport.





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# HEALTHCARE IN THE NORDIC COUNTRIES

The Nordic healthcare system has a long heritage. It is especially well-established with regard to primary and preventive healthcare. These couple into sophisticated occupational health standards which are considered to be models by the outside world. All Nordic countries also have highly-developed hospital services. Nordic healthcare systems are taxation based, and locally administrated with every citizen having equal access to services. All countries, however, require co-payments by patients for hospital care and medicines. In general, the markets have a low level of influence on the functioning of healthcare systems. At a political level, equity and equality are important priorities. At the same time, productivity and efficiency are coming to the political agenda. In spite of a generally high level of commonality, there are some important differences in the Nordic region with regard to healthcare. Some of these are, moreover, growing as each country seeks to adapt to budgetary pressures and an ageing population. Explicit moves to cut down waiting times and improve hospital productivity have been made in Denmark and Finland. Variable user fees for hospitalisation are charged in Finland and Sweden. A brief description and overview of such issues in the four principal Nordic countries is provided below.

### **Denmark**

Like the country itself, Denmark's healthcare sector has three political and administrative levels: the State, the regions and the local municipalities. The healthcare service is organised in such a way that responsibility for services provided by the health service lies with the lowest possible administrative level. Services can thus be provided as close to the users as possible.

The Ministry of Health and Prevention was established on 23 November 2007 when the Ministry of the Interior and Health was separated into two. The Health and Prevention Ministry is in charge of administrative functions related to the organisation and financing of the healthcare system, psychiatry and health insurance as well as the approval of pharmaceuticals.

Earlier in 2007, local government reforms in January saw a system of 15 counties (including the metropolitan area) and 271 municipalities replaced by five regions primarily focused on the healthcare sector and 98 municipalities responsible for a broad range of welfare services.

Overall, within such a decentralised system, the State is responsible for legislation and supervision, while counties and municipalities are charged with operating

health services (the former for hospital service and health insurance, and municipalities for other areas of healthcare, as well as nursing and child/school healthcare). Most hospitals are owned by the counties.

Some private hospitals have contracts with their county, while a handful of mainly small private hospitals operate outside the public hospital system. Specialist hospitals are not organised separately. Neither does Denmark have health centres with hospital beds.

GPs are the primary point of contact for

been rising steadily (it was DKK 1.4 billion in 2006). This has been combined with opening up possibilities for patients to receive treatment at private hospitals or certain accredited hospitals overseas, should waiting times be more than one or two months, respectively.

The reforms have had a significant impact. Waiting times for 18 major surgical procedures fell from 27 weeks in 2002 to 21 in 2005, and an estimated one of eight non-acute patients are now treated outside Denmark.

"To cut down waiting times, the Danish Government has been making supplementary allocations to health services since the turn of this decade."

patients except in an emergency, when they directly use hospital services. Specialist physicians work based on an agreement with a health insurance scheme, and most patients are referred to them by general practitioners.

To cut down waiting times, the Danish Government has been making supplementary allocations to health services since the turn of this decade. The sum has averaged DKK 1.2 billion a year, and has

Since 2004 a move has been made to expand own management of funding by hospitals, with an eventual target of 50% of overall hospital allocations. Though this has led to some uncertainty about hospital budgets, it has contributed to increased efficiency and reduced waiting times.

The federal state block grant still constitutes the most significant element of financing – about 75%. In order to give the

regions equal opportunities to provide healthcare services, the subsidy is determined by a number of criteria such as demographics, and the social structure of each region (the percentage of employed, the elderly, etc.).

Following the local government reforms of January 2007, one novelty is that the municipalities contribute to financing healthcare. The purpose is to encourage them to initiate efficient preventive measures for their citizens with regard to health issues.

Local financing consists of both a basic contribution and an activity-related contribution. Together they constitute approximately 20 percent of total financing of healthcare in the regions.

The basic contribution remains determined by the regions. The maximum limit is fixed by statute (DKK 1,500 per inhabitant at the price and wage level of 2003). The local basic contribution is initially fixed at DKK 1,000 per inhabitant.

The activity-related contribution depends on how much the citizens use the regional health services (hospitalisations and out-patient treatments at hospitals, as well as the number of services from general practitioners). In this way the municipalities that succeed in reducing the need for hospitalisation, etc. through efficient measures within preventive treatment and care will be rewarded.

### **Finland**

Finland has a highly decentralised, threetier system of public healthcare, coupled to a much smaller private healthcare system. Physiotherapy, dentistry and occupational health services are the main areas covered by private care. Employers are legally obliged to provide occupational healthcare services for their employees.

Responsibility for healthcare is devolved to the municipalities (local government, according to the Public Health Act of 1972). Groups of municipalities run specialised central and regional hospitals. Municipalities are also responsible for providing health and social services for elderly people, including assisted living.

Primary healthcare is obtained from district health centres employing general practitioners (GPs) and nurses. These provide most day-to-day medical services and act as gatekeepers to more the more specialized services in the secondary and tertiary care sectors. Secondary/specialist care is also provided by the municipalities through district hospitals.

At the top of the hospital system in Finland is a network of five university teaching hospitals located in the major cities of Helsinki, Turku, Tampere, Kuopio, and Oulu. These provide tertiary care and contain the country's most advanced medical expertise. The university hospitals are also funded by the municipalities, but supported by the national government.

treatment within the specified time limit, it has to be offered at another municipality or a private institution, at no extra cost to the patient.

Finland also has Europe's first law on patients' status and rights. This ensures a patient's right to information, to informed consent to treatment, the right to see any relevant medical documents, and the right to autonomy. Backing this a a Patient's Injury Law, which gives patients the right to compensation for unforeseeable injury that occurred as a result of treatment or diagnosis. To receive compensation, it is sufficient that unforeseeable injury as defined by law occurred. This system has struck a balance between a litigious blame culture like the U.S. and the development

"This system has struck a balance between a litigious blame culture like the U.S. or the development of defensive medical practices as in many parts of Europe."

The Finnish National Public Health Institute and the National Institute for Occupational Health are presently investigating the healthcare sector on issues concerning the structure and division of roles and responsibilities between the State, county councils and the municipalities.

In the public health service system, as mentioned, patients need a referral for specialist treatment, except in the case of emergency. At private clinics, however, patients need no referral to visit private specialists. Physicians working in private clinics can refer their patients either to public or private hospitals.

From March 2005, bar injury, patients are required to be examined and treated within a given time. Appointments have to be given within three working days. Treatment assessments have to be made within three weeks of referral to a hospital. In cases where treatment cannot be given at the first visit to the health centre, it is required to be started within three months, and within six months for specialised treatment. If a patient's own health centre or hospital cannot provide

of defensive medical practices as in many parts of Europe.

As principal providers of healthcare (accounting for two thirds of all spending), the municipalities are funded by national and local taxation. The balance third of spending is met by the national insurance system and private finance (either employer funded or by patients themselves). Barely 10 percent of the income of the private care sector comes from private insurance.

Though spending on healthcare is below the European average, the quality of healthcare service in Finland is high. According to a survey published by the European Commission in 2000, Finland has the highest number of people satisfied with their hospital care system in the EU: 88 percent of Finnish respondents were satisfied compared with the EU average of 41.3 percent.

Finland's National Research and Development Centre for Welfare and Health is establishing a single, accessible, web-enabled repository for healthcare indicators gathered from healthcare providers across Finland.

### **Norway**

The State is responsible for healthcare policy and capacity issues as well as the quality of healthcare through budgets and laws. The State is also responsible for hospital services through regional health authorities – who organise hospitals as health trusts. Municipalities have responsibility for primary healthcare, including both preventive and curative treatment. Regional health authorities and municipalities are free to operate public health services as they deem fit, although budgetary factor limit choices in the real world.

Private healthcare does not play a major role in Norway, due to the high standards and reach of the State system. Some private insurers offer complementary health insurance to those seeking to avoid hospital waiting lists or receive certain treatments such as cosmetic surgery. Private healthcare is also used for substance abuse, as well as dental treatment and certain forms of rehabilitation.

General practitioners (GPs) are gatekeepers in the Norwegian health system. GPs prescribe drugs and provide referrals to specialists and hospitals. They also treat acute and chronic illnesses, and provide preventive care. Citizens can choose the GP of their choice, but can change them up to a maximum of only two times a year. People seeking state medical care must make sure their GP is contracted into the State scheme; others require payment of full (rather than nominal) fees by the patients. Out of normal hours, GPs operate an oncall system. Specialist physicians are also referred to as consultants. GPs refer patients to a consultant if they need specialist diagnosis or intervention.

Norway has 80-plus hospitals located in major towns and cities. Patients are admitted to hospital either through the emergency department or via referral by their GP. Once admitted, treatment is the responsibility of a hospital doctor. In the rare cases where the Norwegian hospital system lacks the expertise to provide care, treatment is arranged overseas at no cost.

The Norwegian health system is funded predominantly through taxes taken di-

rectly from salaries. There is no specific health contribution fund. The Trygdeetaten (National Insurance Administration) is responsible for administering the State National Insurance Scheme (NIS), which guarantees everybody a basic level of health care and welfare (disability, unemployment, pension). All citizens and residents of Norway must contribute to the NIS.

In return, there are relatively few fees for using the State system. Inpatient hospital treatment is free. However, visits to doctors and specialists as well as purchases of prescription medicine incur small copayments. So do radiology and laboratory tests. There are nevertheless a number of exemptions, not least those afflicted by chronic diseases.

"Having less people treated in hospitals, for less time, has allowed Sweden to plough more investment into community services."

### Sweden

The Swedish healthcare system is organised in seven sections: proximity or close-to-home care (this covers clinics for primary care, maternity care, out-patient mental healthcare, etc.), emergency services, elective care, hospitalisation, out-patient care, specialist treatment and dental care.

The healthcare system is administered by 21 councils, of which 18 are at the county level and three are regional. The population in these 21 areas ranges from 60,000 to 1,900,000. The councils have considerable freedom in planning for the delivery of care and this is one explanation for significant regional variations.

The role of the central government is to establish principles and guidelines for care and to set the political agenda by means of laws and regulations. This is also achieved by means of agreements with the Swedish Association of County Councils and Local Authorities.

At the national level, several expert bodies play a role in planning the healthcare. Socialstyrelsen (National Board of Health and Welfare) is the central government's key supervisory authority. The others are Hälso-och sjukvårdens ansvarsnämnd (the Medical Responsibility Board), Statens beredning för medicinsk utvärdering (Swedish Council on Technology Assessment in Healthcare), Läkemedelsförmånsnämnden (the Pharmaceutical Benefits Board), Läkemedelsverket (the Medical Products Agency) and the state-owned Apoteket AB chain of pharmacies.

Hospitals are run by both county and regional authorities. The former include specialised hospitals covering the entire county and general hospitals covering a part of the county.

Medical treatment is provided at both hospitals and outpatient clinics. Specialised treatment is provided by the regional hospital service.

There is a small presence of private (but publicly-financed) healthcare in Sweden, along with political controversy. About one-third of medical consultations are with private medical practitioners.

Regulations, waiting times and patient fees vary in the different Councils. The national guarantee of care states that a patient should be able to get an appointment with a primary care physician within five days of contacting the clinic. If referred to a specialist by the GP, they should get an appointment within 30 days, and if treatment is deemed necessary by the specialist, it should be given within 90 days. However, urgent cases are always prioritised and emergent cases are treated immediately.

The main criticism is that waiting times are too long in practice, especially for low priority non emergency surgery such as hip and knee replacement, where the guaranteed time is 90 days.

Nevertheless, Sweden has a far higher rate of efficiency in its healthcare service delivery than most EU members. It has the EU's highest rate of physicians per capita, at 3.3 per 1,000; although this slightly lags behind non-EU Nordic neighbour Nor-

way, it compares to a rate of two in Britain. Such a ratio allows patients to have quick and easy access to healthcare professionals.

Sweden also recognised in the mid-1990s that health services had to change to meet increasing demand, especially as people began to live longer. As hospital treatment tends to be expensive compared to GPs or outpatient/community care, it started to push for more patients to be treated in pri-

mary care. Over the last decade, GP visits have steadily grown while specialist interventions have fallen. Sweden has also sought to drive patients more quickly through the hospital system, a methodology now acknowledged to be superior (not least in terms of reducing nonsocomial infections).

Having less people treated in hospitals, for less time, has allowed Sweden to plough more investment into community services, which was one of its goals to begin with.

Overall, the Swedish State finances the bulk of health care costs (about 95%), with the patient paying a small nominal fee for examination. Hospitalisation charges for patients are capped at SEK 80 per day. Patients under 40 pay only half the cost for the first 30 days of each sickness period.

Figure 1. Comparison of national health indicators in the Nordic countries

	DENMARK	FINLAND	NORWAY	SWEDEN
Population (million: 2008)	5.5	5.25	4.66	9.06
Live births/female (2008)	1.74	1.73	1.78	1.67
Deaths/1,000 (2008)	10.25	10.0	9.33	10.24
Life expectancy in years (2008)	78.3	78.97	79.95	80.86
GDP (billion Euros: 2008)	233.3	186.2	283.0	
(2007)	328.3			
Total healthcare expenditure (% GDP: 2004)	9.0%	NA	9.7%	9.5%
Total healthcare expenditure per capita (PPP dollars: 2004)	2,838	2,275	3,862	2,875
% of healthcare system financed by public funds: (2004)	82.30%	76.6%	78% (2005)	84.9%
Number of general hospitals (2003)	57	NA	28	NA
Number of CT scanners (per million inhabitants: 2004)	14.6	14.2	NA	NA
Number of MRIs (per million inhabitants: 2004)	10.2	14	NA	NA
Number of acute care beds (per 1,000 inhabitants: 2006)	3.1	2.4	3.1 (2003)	2.8
Length of stay (average in days: 2006)	3.4	4.2	6 (2004)	6.0
Number of physicians (per 1,000 inhabitants: 2004)	3.6 (2003)	2.4	3.5	3.3 (2003)
Number of nurses (per 1,000 inhabitants: 2004)	7.0 (2003)	7.6	14.9	10.3 (2003)
Percentage of households with Internet access	75% (2005)	54% (2005)	69 % (2006)	77% (2006)
Percentage of individu- als using the Internet for interacting with public authorities	Obtaining information 42,5%, Downloading forms 16,4%, Returning filled forms 13,9% (2004)	Obtaining information 44,6%, downloading forms 21,5%, returning filled forms 11,2% (2005)	Obtaining information 52.1 %, Downloading forms 30.1 %, Returning filled forms 28.2 % (2006)	Obtaining information 48,7%, Downloading forms 30,7% (2005), Returning filled forms 21,4% (2005)

Source: European Central Bank, OECD, WHO, EU Commission and national statistical agencies

# CARDIOLOGY IN THE NORDIC COUNTRIES

### Overview of the National Societies of Cardiology in Norway, Sweden, Finland and Denmark



The Norwegian Society of Cardiology (NSC) was founded in 1969. Its main activities can be divided into:

Organisational: Provides advice and support for the Norwegian Medical Association related to education in cardiology, professional advice and defining national priorities for healthcare. Maintains international contact with the European Society of Cardiology (ESC).

Educational: Organises national meetings three times per year, and a regular Nordic cardiology meeting. Coordinates annual meetings for all cardiology trainees in Norway.

**Registries:** Organises the national pacemaker registry.

Publications: Runs 'Hjerteforum', the journal of the Norwegian Society of Cardiology which is published four times per year. In addition, Hjerteforum publishes Norwegian PhD. theses.

Working groups: Leads working groups for congestive heart failure, invasive cardiology, electrophysiology and echocardiography.

For the major part, cardiology services in Norway are under public finance. There are a few cardiologists without public financial support. As of January 4, 2010, there are 316 cardiologists currently practicing in Norway. Approximately 90 percent are members of the NCS.

The department of cardiology at Oslo University Hospital Rikshospitalet has approximately 15 senior consultants and 13 junior consultants. Activities include interventional cardiology with PCI, percutaneous

aortic valves, congenital heart disease, heart transplantations and electrophysiology (including ICDs, CRTs and radiofrequency ablations). We have 10 coronary care unit beds and 15 on the regular ward.

To qualify as a practicing cardiologist in Norway, approval in internal medicine, which takes six years, is the first requirement. Three years of study in cardiology is needed in addition, but some overlap is possible, so that the minimum time required for education after internship is eight years. Candidates need to gain experience in all fields of cardiology, and trainees must obtain practical skills – for example, 50 independent and 150 assistant catheterisation procedures, 300 echocardiograms, 300 exercise ECG tests. There is no final exam, but the Norwegian Medical Association approves cardiologists after application.

Information kindly provided by: Prof. Ketil Lunde, Department of Cardiology, Oslo University Hospital, Oslo, Norway

### Swedish Society of Cardiology

The Swedish Society of Cardiology was founded in 1947 and includes over 900 active members.

Prof. Per Tornvall has been President of the society for the past three years and will be replaced by Prof. Lena Jonasson in April, 2010.

The society has six working groups:

- Coronary heart disease;
- Heart failure:
- GUCH;

- PCI;
- Arrhythmias, and
- Ethics/health economics.

The primary focus of the society is on the education of the profession, including training to become a cardiologist and inspections of the different cardiological training centres. The society arranges two meetings per year; the Cardiovascular Spring Meeting and an update meeting during the fall. Many of its members are active in ESC as FESC and in a variety of working groups and associations. In 2010, the society's national update meeting will take place in the European Heart House, 7 - 10 October.

The Swedish Heart Organisation encompasses five Swedish specialty societies: the Society of Cardiology; the Society of Clinical Physiology; the Society of Thoracic Anaesthesia and Intensive Care; the Society of Thoracic Radiology and the Society of Cardiac Surgery.

Information kindly provided by: Prof. Per Tornvall, President of the Swedish Society of Cardiology and also Associate Professor of Cardiology, Department of Cardiology, Karolinska University Hospital Solna, Stockholm, Sweden

### Finnish Cardiac Society (FCS)

### **Key Facts**

 Number of Cardiologists (Jan 2009): 227 altogether, from which 199 are in active working age. Out of the working aged cardiologists, 49 are women and 150 are men.

(Source: Finnish Medical Association).

 Number of Cardiologists in Training: 38 training positions in five university hospitals and their regional/central hospitals.

The founding meeting of the Finnish Cardiac Society (FCS) was held on November 13, 1967, in Helsinki. There were 37 founding fathers present. There are currently around 760 members, of which around 210 are consultant cardiologists and 38 are registrars in cardiology.

The remaining members include doctors with a special interest in cardiology (e.g, cardiac surgeons, anaesthesiologists, paediatric cardiologists, specialists in internal medicine, clinical physiology specialists, paediatrics and radiology) and other professionals with an interest in cardiovascular medicine. The society has 12 active working groups. Its board is composed of nine voting members elected by society members at the annual business meeting in January every even-numbered year. In addition, the board consists of the non-voting Editor-in-Chief of the membership journal Sydänääni (Heart Sound). Executive and course secretaries of the society also attend the board meetings. The board has eight meetings yearly.

The FCS has been a member of the European Society of Cardiology since 1968 and is an affiliated member of the American Heart Association and the World Heart Federation. The Finnish Cardiac Society works closely with the Finnish Heart Association in the role of promoting cardiovascular health in Finland. It organises several educational meetings in cooperation with other national medical associations and/or societies, such as the Finnish Hypertension Society, Finnish Society of Internal Medicine, Finnish Society for Thoracic Surgery and Finnish Society of Anaesthesiologists. The FCS also has 38 industrial members representing both the pharmaceutical and device companies in the field of cardiology.

The society's primary focus is on its scientific and educational aspects. In 2008, the FCS organised 143 educational events, with a total of over 4,300 participants. Its main meetings are the autumn meeting held in

October, a spring meeting in March and an annual meeting in January.

The FCS grants around 90,000 euros yearly to Finnish professionals in the field of cardiology to financially support Finnish research and presenting research results in the field of cardiovascular diseases.

The FCS has 12 working groups dedicated to variety of specific areas in cardiology. Each one has a nucleus composed of a Chairman, Vice-Chairman and Secretary, which is changed every second year.

The society publishes a journal entitled "Sydänääni", which is published five times per year with one central themed issue per year. The journal is distributed to society members as well as supporting industrial members and other groups such as medical directors of University and central hospitals in Finland.

### Danish Society of Cardiology (DCS)

The Danish Society of Cardiology (DCS) was established on May 6, 1960, at the initiative of Professor Erik Warburg, due to the development of cardiology in the Nordic countries, and the parallel development of heart surgery. The first meeting of DCS was held on March 24, 1961, including six oral presentations and 33 participants.

The aims of the DCS are to:

- Increase theoretical and practical knowledge and progress within cardiovascular disease, arrange scientific meetings for its members and provide continuing medical education;
- Advise the national authorities regarding medical education in cardiology, and
- Represent the specialty of cardiology in relation to Danish medical authorities and corresponding global organisations.

The main activities of the Danish Society of Cardiology (DCS) are educational events and initiatives to improve the treatment of cardiovascular diseases. Twelve working groups, matching those of the ESC lead these initiatives by arranging educational programmes, elaborating position papers and national guidelines and endorsing ESC guidelines with respect to national requirements.

One of the most challenging tasks is to argue for a consistent focus on the burden of cardiovascular disease in Denmark. This goal is achieved by a close collaboration with the National Board of Health and the Danish Heart Foundation.

A very important evolvement in recent years is the introduction in 2005 of the "National Treatment Guideline for Heart Diseases", a web-based (PDA downloadable) guideline, which is updated every February, and which covers the latest international guidelines regarding heart disease. Also, ESC guidelines are increasingly endorsed in the national guidelines to the benefit of our patients.

The Board of the DCS comprises 10 cardiologists representing Denmark's five geographic regions, with representatives of university heart centres and regional hospitals with cardiology specialties. Board members meet monthly to discuss current tasks, updates, progress and future strategy.

The Danish Society of Cardiology has its own membership journal, "Cardiologisk Forum", which is in Danish and published quarterly. The journal is mailed to each member and also available online from the DCS website (only in Danish).

The two-day annual meeting is held in May and always includes a "Young Investigators Award" competition. Five abstracts representing the foremost cardiovascular science in Denmark are selected for oral presentation and then compete for grants in both basic science and clinical science categories. A research prize is awarded, and the programme also includes a number of lectures mainly related to recent scientific progress, hot topics in the national healthcare system, policies and certain economic aspects of cardiology. The annual autumn meeting is held in October or November with a one-day programme of scientific lectures related to recent progress, hot topics in the national health care system, policies and economical aspects of cardiology.

The DCS has a close relationship with the ESC, and became a member in June 1960, right after the creation of the DCS, as one of the founding countries. Automatic membership of the ESC is promoted actively to the DCS members.

# CARDIOLOGY MANAGEMENT

### **INDUSTRY** NEWS

### **EUROPEAN APPROVAL GIVEN TO ST. JUDE MEDICAL ICD AND CRT-D DEVICES**

St. Jude Medical implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy defibrillators (CRT-D) have been given the European CE Mark approval.

The products, including the Fortify(TM) and Fortify ST ICDs as well as the Unify(TM) CRT-D, will be fully launched in Europe this spring. Their reduced size, the smallest available device footprint in the industry, allows the products to be implanted through a smaller incision, as well as limits the number of connections from the defibrillation lead and the device, improving patient comfort.

ICDs and CRT-Ds help ensure effective therapy and provide additional disease management monitors for heart failure patients or patients at risk for sudden cardiac arrest.

The devices feature the highest energy level available in the industry. Energy capability of the device is especially important for patients with an enlarged heart, low ejection-fraction, advanced heart failure or have previously demonstrated a high defibrillation threshold.

The Unify CRT-D and Fortify ICD include the CorVue(TM) pulmonary congestion monitoring algorithm which alerts physicians when a patient's heart failure may be worsening through changes in electrical signals.

### **EDWARDS INITIATES STUDY OF AORTIC VALVE SURGERY SYSTEM**

Edwards Lifesciences has completed the first in-man procedures of minimally invasive aortic valve surgery system and has initiated a feasibility study that is now actively enrolling in Europe.

Known as Project Odyssey, the system uses the Carpentier-Edwards PERIMOUNT

Magna Ease tissue heart valve design to create a new valve platform. The system enables a faster procedure, shorter patient time on cardiopulmonary bypass and a smaller incision.

The feasibility study for Project Odyssey, TRITON, is part of Edwards' corporate strategy to couple its expertise in heart valves with innovation in delivery. Ideally, TRITON will improve the valve surgery experience for both surgeons and patients.

### **MEDTRONIC TO ACQUIRE INVATEC** AND AFFILIATED COMPANIES

Meditronic, Inc. has signed an agreement to acquire Invatec, a developer of technologies for the interventional treatment of cardiovascular disease, and two affiliated companies.

Expanding its product offering and adding franchise and pipeline, the agreement could be worth 500 million dollars, 350 million initially and up to 150 million with further Invatec achievement.

Invatec will add products such as stents and angioplasty balloons, while the affiliate companies, Fogazzi and Krauth Cardiovascular, will provide polymer technology and distribution services respectively.

### MEDTRONIC NON-SURGICAL **VALVE REPLACEMENT RECEIVES** FDA APPROVAL

The Melody® Transcatheter Pulmonary Valve manufactured by Medtronic Inc. has received U.S. Food and Drug Administration (FDA) Approval, the first transcatheter heart valve to do so.

The device is designed for patients with a malformation of their pulmonary valve. While these patients often require openheart surgery, the Melody valve is delivered through a catheter requiring only a small incision.

Since receiving European CE approval

in 2006, the Melody valve has been used in more than 1.100 cases.

### **BIOSENSORS BIOMATRIX FLEX** (TM) RECEIVES CE MARK **APPROVAL**

BioMatrix Flex(TM), a new version of the Biosensors BioMatrix drug-eluting stent system, will be made available over the coming months upon European CE Mark approval.

The BioMatrix Flex combines the abluminal biodegradable polymer and proprietary limus drug, Biolimus A9(TM). The BioMatrix stents first received approval in 2008 and also include a smaller-diameter version that was approved last year.

Also recently, the BioMatrix stent system received approval for reimbursement in France through addition to the Liste des Produits et Pestations Remboursables (LPPR).

Already the BioMatrix stent system has been helping patients with coronary artery disease in other parts of the world including Latin America and Asia.

### **GE HEALTHCARE APPOINTS NEW CHIEF MEDICAL OFFICER**

William (Pepper) Denman has been appointed Chief Medical Officer (CMO) at GE Healthcare, the most senior physician in the company.

The former CMO and Vice President of Medical Affairs for Covidien, Denman will provide clinical direction to GE Healthcare as the new CMO. Working primarily with the Global Quality, Regulatory and Medical organisation, Denman will focus on improving process rigor in clinical trial design, strengthening academic research partnerships and improving medical risk assessments. Denman also will lead all clinical and evidence generation strategies, driving technology and scientific synergies across all of GE Healthcare.

Denman is currently involved in multiple clinical and basic science research projects at Massachusetts General Hospital and Harvard Medical School. He received his Doctor of Medicine at the University of Aberdeen (United Kingdom).

### SIEMENS PRESENTS INTERVEN-TIONAL NEURADIOLOGY IMAGING

Siemens has developed new functional imaging that displays cerebral blood flow during interventional procedures.

Labeled syngo Neuro PBV IR (Parenchymal Blood Volume, Interventional Suite), the technology allows review of parenchymal blood flow during minimally invasive interventions in the brain for the first time. Neuroradiologists will now be able to see the condition of the cerebral tissue directly in the angio suite of stoke patients.

Unlike traditional CT acquisition, clinicians will have blood volume data for the entire brain, and be able to review the information from any orientation, axial, coronal, sagittal, etc. The advantages will be seen in stroke treatments, as well as tumor biopsy and treatment, tissue embolisation and vasospasm therapy.

### BIOTRONIK SIGNS EXCLUSIVE DISTRIBUTION AGREEMENT WITH ENDOSENSE

Biotronik has announced it will be the exclusive distributor of Endosense's Tacti-Cath® in all major markets outside the United States, Japan and Asia.

The TactiCath® is a force-sensing ablation catheter that was granted CE mark approval for atrial fibrillation and supraventricular tachycardia indications in 2009. Supported by acute and chronic evidence, the catheter gives physicians a real-time, objective measure of contact force for cardiac ablation procedures. The partnership brings together Biotronik, a manufacturer of implantable cardiac devices and wireless remote monitoring technologies, and Endosense, a Geneva-based company that specialises in catheter ablation technology.

### MAQUET CARDIOVASCULAR INITIATES OPTION STUDY

Maquet Cardiovascular LLC initiates OP-TION study designed to address conduit quality of endoscopically-harvested grafts.

OPTION, or the Optimal Improvement of Vein Graft Patency Long Term by the Implementation of Novel Endoscopic Harvesting Techniques Study, will evaluate the equivalence of endoscopic vessel harvesting (EVH) in coronary artery bypass graft (CABG) compared with historical data for open vein harvesting.

The 100-patient, single-centre study will evaluate the vein graft patency at one month and one year after CABG surgery. In the U.S., EVH is used in around 80 percent of CABG procedures.

## SORIN GROUP JOINS "BAMBINI CARDIOPATICI NEL MONDO" IN PROVIDING CARDIAC CARE TO DISADVANTAGED CHILDREN

Sorin Group will work with the non-profit organisation Bambini Cardiopatici nel Mondo in order to serve disadvantaged children with congenital heart disease.

Sorin Group has guaranteed financial contributions, not less than 600,000 euros over three years, as well as donation of medical devices and volunteer participation by its employees. These humanitarian activities are a part of Sorin Group's first Global Cause.

### VOLCANO RECEIVES CE MARK FOR OPTICAL COHERENCE TO-MOGRAPHY IMAGING SYSTEM

Volcano Corporation has received the CE mark approval for their Optical Coherence Tomography (OCT) imaging system and catheter. The OCT line is used in coronary imaging and lesion assessment, complimenting Volcano's existing products such as its IVUS imaging catheters and pressure guide wires.

### UK REVIEWS DRONEDARONE FOR ATRIAL FIBRILLATION

UK cardiologists among others are petitioning the UK National Institute for Health and Clinical Excellence (NICE) to support dronedarone for treatment of recurrent atrial fibrillation (AF).

The use of the antiarrhythmic drug, Multaq, produced by Sanofi-Aventis was discouraged by NICE in December on the grounds that it was more expensive and not as effective as others in the market. UK cardiologists, nurses, patients and industry are now encouraging it to be made available for prescription by the National Health Service (NHS). Multaq® was approved by the European Union in September 2009.

Already discussed in Parliament, comments from interested parties are being reviewed and a stakeholder inquiry is underway. Efforts have been coordinated by the Atrial Fibrillation Association and Heart Rhythm UK receiving more than 100 doctors' signatures on the petition. Sanofiaventis has taken part of the activities, but has not contributed financially. A final guidance to the NHS will be issued by NICE in the weeks following their second panel meeting that took place 24 February.

### MERGE INTRODUCES PATIENT-FOCUSED IT SOLUTION

Merge has announced the launch of a fullservice kiosk focused on the patient in healthcare facilities. The automated technology guides patients through the checkin process with the ability of an avatarbased agent. The deployment of the kiosk came from the success of similar technologies in other industries.

The system sets the appropriate alerts, updates a patients' status and scans required documents, all within the normal workflow of the clinic. The kiosks have seen positive results and through their use healthcare facilities hope to establish loyalties with their customers with the improvements in operational efficiency.

### **KEY SEMINARS AND CONFERENCES**

### **APRIL**

#### 8 - 9 April

Spring Meeting of the Netherlands Society of Cardiology

www.nvvc.nl

ARNHEM, THE NETHERLANDS

8 - 10 April

76th Annual Meeting of the German Cardiac Society

www.dgk.org MANNHEIM, GERMANY

9 - 12 April

**XXXI Portuguese Congress of Cardiology** 

www.spc.pt/spc LISBON, PORTUGAL

15 - 17 April

Cardiac Pacing, ICD and CRT

www.escardio.org SOPHIA ANTIPOLIS, FRANCE

21 - 23 APRIL

**Swedish Cardiovascular Spring Meeting** 

www.malmokngressbyra.se GOTHENBURG, SWEDEN

23 - 25 April

5th Clinical Update on Cardiac MRI & CT

http://cannes2010.medconvent.at CANNES, FRANCE

25 - 27 April

**Biomarkers in Heart Failure 2010** 

www.escardio.org SOPHIA ANTIPOLIS, FRANCE

### MAY

5 - 7 May

**EuroPRevent 2010** 

www.escardio.org/congresses/europrevent-2010 PRAGUE, CZECH REPUBLIC

5 – 8 May

**Annual Congress of the Hungarian Society of Cardiology** 

www.mkardio.hu BALATONFÜRED, HUNGARY

6 - 8 May

**Annual Meeting of the Danish Society of Cardiology** 

http://www.cardio.dk NYBORG, DENMARK 6 - 8 May

Norwegian Society of Cardiology Spring Meeting 2010

www.hjerte.no OSLO, NORWAY

16 - 19 May

Rome Cardiology Forum 2010

www.escardio.org

19 - 22 May

41st National Congress of the Italian Society of Hospital Cardiologists

www.anmco.it FLORENCE, ITALY

20 - 22 May

Weinstein Cardiovascular Development Conference

weinstein.heartrepair.eu AMSTERDAM, THE NETHERLANDS

25 - 28 May

EuroPCR 2010

www.europcr.com PARIS, FRANCE

27 - 29 May

8th Annual EuroCMR Meeting 2010

eurocmr2010.medconvent.at FLORENCE, ITALY

29 May - **01** June

**Heart Failure 2010** 

www.escardio.org

#### JUNE

2 - 5 June

**Annual Meeting of the Austrian Society of Cardiology** 

www.atcardio.at SALZBURG, AUSTRIA

2 - 5 June

**International Conference on Pulmonary Circulation 2010** 

www.pc2010.eu
PRAGUE, CZECH REPUBLIC

7 - 9 June

**BCS Annual Conference and Exposition 2010** 

www.bcs.com

MANCHESTER, UNITED KINGDOM

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### COMING IN THE NEXT ISSUE

#### **COVER STORY**

**Intervention Management** 

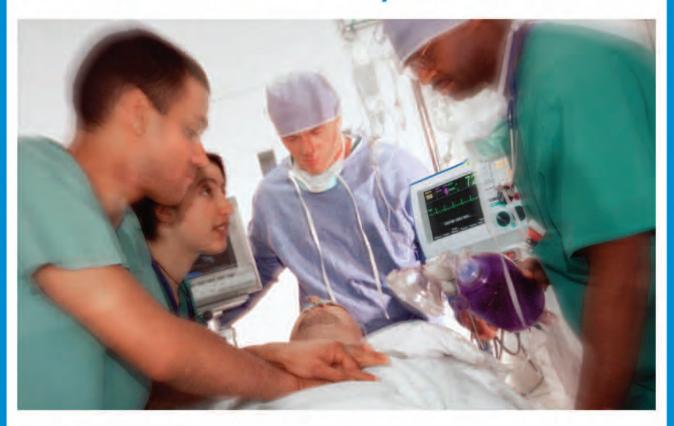
CENTIDES

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COUNTRY PROFILE

**Cardiology in the Netherlands** 

# The worst time to find out your defibrillator isn't ready is at the code.





You've been there. A code is chaotic. People are demanding action, and a life hangs in the balance. You reach for the defibrillator and discover it's not ready. It could be delays and confusion from multiple cables, compromised or missing electrodes, depleted batteries, unclear controls, or confusing alarms.

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