



# CARDIOLOGY MANAGEMENT

Volume 2 - Issue 2, Winter 2008

## PATIENT ACCESS to Medical Technology in Europe

- Cardiology in the US
- Developments in Cardiac CT
- Marketing Healthcare Services



# Pioneers of Vision

Outstanding!  
Up to 24-inch  
detector diagonals

## RADspeed Safire

High-tech  
radiographic system

## BRANSIST Safire

Cardiology system

- for cardiology and interventions
- highest acquisition rate
- fastest rotation-DSA (60°/sec)
- fast, low dose acquisition

## Opescope

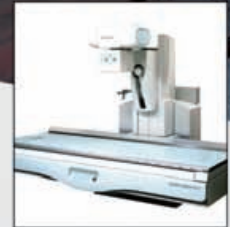
Mobile  
surgical C-arm

## MobileArt

Mobile X-ray system,  
motor-driven

## Sonialvision Safire II

High-performance  
RF universal system,  
remote-controlled



With its visionary technology, Shimadzu has always offered physicians new possibilities for diagnosis, such as the development of the first commercial X-ray instrument in Japan soon after the discovery of X-rays. Countless patents and world premieres, setting the standard today, have contributed to Shimadzu's leading role in diagnostic imaging.

### Shimadzu is also a pioneer in the groundbreaking direct-conversion FPD technology:

- direct conversion of X-rays to digital image data
- cassettes and X-ray films are unnecessary
- much higher image quality and expanded diagnostics
- radiation dose reduced by half
- fully digital and faster data handling
- full DICOM-compatibility.

Direct-conversion FPD is the technology of the 21<sup>st</sup> century. It is the present as well as the future. Shimadzu's X-ray and fluoroscopy systems are economical, meet the highest diagnostic requirements and are easy to operate.

Shimadzu Europa GmbH  
Albert-Hahn-Str. 6-10 · 47269 Duisburg, Germany  
Phone: +49(0)203-7687-0 · Fax: +49(0)203-766625

[www.shimadzu.eu](http://www.shimadzu.eu)



**SHIMADZU**

*Solutions for Science*  
since 1875

# Editorial

Dear Readers,

Medical technology is constantly widening the diagnostic and therapeutic horizons in our professional lives. It provides hope for the patient who looks to the rapidly developing medical technology of tomorrow for a solution to his or her complex health problems today.

Simultaneously, medical technology represents a remarkable sector of corporate activity, on both sides of the Atlantic. Focusing on Europe, we recognise that approximately 11,000 companies are active in the field of medical technology, with the greatest number of these based in the United Kingdom. According to 2005 data, it is estimated that the medical technology industry in Europe has sales of approximately 63.6 billion euros, with an annual growth rate that averages between 5 and 6%.

Undoubtedly, of particular importance to the European Union, are the investments that insurance companies make in every form of medical technology. Notwithstanding however, the important developments in the field, the question arises of whether all Europeans have equal access to medical technology?

Quite simply, the answer is no. Differences exist between member countries and frequently even between regions within the same country. Within the same country, differences between the economic sectors are hardly rare. This disappointing observation is somewhat tempered by the fact that generally, European citizens have one of the best average ratios of access to medical technology worldwide.

If an expert were to attempt to investigate the reasons and causes leading to this heterogeneity in access to medical technology, he would inevitably have to analyse complex social, professional and economic issues. All these factors lead to a heterogeneous reality, in which evidence-based medicine and its pillar, the guidelines, are implemented to varying degrees, in diverse ways, in different populations.

In Europe, it is a fact that the financial reality varies significantly, since the gross domestic product per capita ranges from 72,000 euros in the northern European countries to approximately 4,000 euros in other countries. Are the reasons behind a varying degree of access to technology mainly financial? Perhaps, but not entirely. If one observes the traditionally well-developed national health system in the United Kingdom, significant differences also exist - for example, its low number of invasive cardiology and electrophysiology laboratories.

Differences in access to medical technology are often linked to regional, political and to some degree, arbitrary decisions, as well as rationales that eschew from the spirit of the guidelines and incomprehensive postgraduate training; to name but a few. Scientific bodies are systematically trying to improve this situation. Various surveys that are developed and run by scientific bodies, like the Euroheart Survey, aim at evaluating the existing realities and subsequently at contributing to the harmonisation of medical practice in Europe. This is an aim we share and the reason we focused on "Patient Access to Medical Technology" in this issue.

Yours faithfully,

Panos E. Vardas, MD, PhD  
Professor of Cardiology



*Editor-in-Chief*  
*Professor Panos Vardas*

How can we improve the workflow in our cath lab?

Is there a way to keep better track of my department?

How can we improve the reporting process and report availability?

Whatever you ask, whatever your task:  
**syngo Suite provides the answers.**

As part of the *syngo*® Suite, *syngo Dynamics* is a multi-modality, dynamic image processing and archiving system, using evidence-based reporting to help improve the efficiency of your clinical procedures. The scalable solution effectively integrates patient digital imaging information throughout the cardiology department and beyond – providing patient images and data when and where they are needed. *syngo Suite*. Living workflow intelligence.

[www.siemens.com/syngo-suite](http://www.siemens.com/syngo-suite) +49 69 797 6420

Answers for life.

**SIEMENS**

- 1 Editorial
- 5 EU News

## COVER STORY

### PATIENT ACCESS TO MEDICAL TECHNOLOGY IN EUROPE

- 8 Access to Medical Technology Differs Across Europe: Survey Shows Variety of Causes for Discrepancies Between Guidelines and Practice Prof. L. Rydén
- 10 Access to Cardiovascular Technology Across Europe: The Role of Financing Dr. G. Cappellaro
- 12 Optimising Access to Cardiovascular Technology in Europe: The Case for Device Implantation Rates Mr. M. Karamalis
- 15 Market Access in European Union Countries: Pricing and Reimbursement of New Healthcare Technologies Mr. N. Maniadakis

## FEATURES

- 22 Cardiac CT: A Snapshot of Coming Developments Dr. J. Lauanders
- 24 Setting Up a Heart Failure Clinic: Ensuring Operational Efficiency Prof. G. De Keulenaer
- 26 Review of Anticoagulants: Improving the Management of Thromboembolic Prevention in Routine Practice Prof. G. Turpie
- 28 Management Challenges of Cardiologists in Latvia: Taking Steps to Modernise Facilities Ass. Prof. A. Erglis

## COUNTRY FOCUS: CARDIOLOGY IN THE UNITED STATES

- 38 Overview of the Healthcare System in the United States: Disparity in Access Continues to Provoke Prof. S. Sujanthy Rajaram, Prof. C. Bekes
- 40 Motivating Patients to Get Involved in Their Health: EUROASPIRE III Trial Mirrors US Struggle to Empower Patients Dr. M. Cobble
- 42 Profile of the American Heart Association: Building Healthier Lives

## HEALTHCARE ECONOMICS

- 20 Marketing your Healthcare Services: What you Need to Know Dr. L. Ruhmann, Prof. M. Goyen

## INDUSTRY NEWS

- 46 An Overview of the Latest Updates from Technology & Industry

## CARDIOLOGY LEADERS

- 33 Interview with Prof. R. Ferrari

## CONFERENCE AGENDA

- 48 Overview of Upcoming Congresses and Meetings

### Editor-in-Chief

Prof. Panos Vardas

### Editorial Board Members

Prof. Gunter Breithardt, Germany

Prof. Michele Brignole, Italy

Prof. Hugo Ector, Belgium

Prof. Michael Glikson, Israel

Prof. Peter Kearney, Ireland

Prof. Alexandras Laucevicius, Lithuania

Ass. Prof. Nikos Maniadakis, Greece

Prof. Chu Pak Lau, China

Prof. Fausto J. Pinto, Portugal

Prof. Piotr Ponikowski, Poland

Prof. Silvia G. Priori, Italy

Prof. Amiran Revishvili, Russia

Prof. Massimo Santini, Italy

Prof. Udo Sechtem, Germany

Prof. Dan Tzivoni, Israel

Prof. Alec Vahanian, France

Dr. Rob van den Oever, Belgium

© Cardiology Management is published four times per year. The publisher is to be notified of cancellations six weeks before the end of the subscription. The reproduction of (parts of) articles is prohibited without the consent of the publisher. The publisher does not accept liability for unsolicited material. The publisher retains the right to republish all contributions and submitted materials via the Internet and other media.

### LEGAL DISCLAIMER

The Publishers, Editor-in-Chief, Editorial Board, Correspondents and Editors make every effort to ensure that no inaccurate or misleading data, opinion or statement appears in this publication. All data and opinions appearing in the articles and advertisements herein are the sole responsibility of the contributor or advertiser concerned. Therefore the Publishers, Editor-in-Chief, Editorial Board, Correspondents and Editors and their respective employees accept no liability whatsoever for the consequences of any such inaccurate or misleading data, opinion or statement.



## **Simplicity is a 12-lead ECG that reaches the hospital before your patient does.**

**Philips cardiology solutions** are designed to help you deliver timely, effective care to your acute cardiac patients. For patients with suspected STEMI, you can wirelessly transmit 12-lead ECG from the ambulance to the emergency department and cardiologist. Sharing this information helps ensure your cath lab is activated only when needed. Saving lives and resources just makes sense.

[www.philips.com/acc](http://www.philips.com/acc)

**PHILIPS**  
sense and simplicity

# EU NEWS

## WHO GOVERNING BODY TO MAKE DECISIONS AFFECTING HEALTH SYSTEMS

AUTHOR

**Helicia Herman**  
EU Affairs Editor

The need to strengthen health systems so that they can respond quickly and flexibly to the growing number of new challenges was on the agenda of the WHO's European governing body, the WHO Regional Committee for Europe. Attended by over 250 health officials from the WHO European Region, its annual session took place in Tbilisi, Georgia from September 15 - 18.

The Regional Committee considered several critical health issues and adopted important resolutions. Member States' representatives discussed the governance of health systems, health promotion, the social determinants of health, noncommunicable diseases, child and adolescent health, and climate change.

The Regional Committee gives priority to making health services accessible to all, particularly to those who cannot afford to pay for healthcare. Opening the session on 15 September, the Prime Minister of Georgia, Vladimer Gurgenedze, said that health is an important tool in reducing poverty. Providing his country's population, especially people who live below the poverty line, with access to social and health protection is among the Government's top objectives.

### Increasing Health Systems' Capacities

One of the Regional Committee's goals is to increase health systems' capacities to respond to health emergencies.

"Governments made important achievements in this field by signing the Tallinn Charter in June this year. When a crisis happens, the malfunctioning of a health system puts the health of the world in danger. There is no room for complacency – we have a lot of work to do to carry out the plans mapped out in Tallinn," says Dr. Marc Danzon, WHO Regional Director for Europe.

Health systems are the focus of other items on the Regional Committee's agenda. Representatives are exploring the driving forces behind better health system performance, the difference good governance can make, and the health sector's role in encouraging people to adopt healthier behaviour, including abstinence from smoking, weight management, blood pressure control and regular exercise.

The Regional Committee is also taking stock of progress made across the WHO European Region and setting new goals for the years ahead. The Regional Director's report on the work of the WHO Regional Office for Europe in 2006 – 2007 showed that many goals had been successfully achieved but much work remained.

Presenting the report and describing the Regional Office's activities in 2008, Dr Danzon cited encouraging trends in such areas as tackling noncommunicable diseases and the provision of health services for vulnerable population groups. The report highlights significant increas-

es in the Regional Office's presence in countries and in the share of its budget devoted to country work.

### EU to Study Electronic Chips for eHealth

The Commission has decided to study the options for using Radio Frequency Identification (RFID) technology in healthcare, with applications ranging from the identification of patients in hospitals to tagging pharmaceutical products.

The Commission recently published a call for tenders for a study on requirements and options for actions in Radio Frequency Identification (RFID) technology in healthcare. The main objective of the study is to assess the expected features of RFID applications in the healthcare market and to build future scenarios in the field. It is also set to identify possible obstacles and needs for policy actions or specific research activities on the subject.

In healthcare, RFID is used primarily for tagging pharmaceuticals. In hospitals, RFID systems are used, for example, to identify patients and to permit relevant hospital staff to access medical records. The systems are said to save lives, prevent errors, save costs and increase security.

Results of a recent Commission consultation on RFID show privacy, health and environmental risks as the main stakeholder concerns with regard the use of this technology. As to the use of RFID-based

## EU NEWS

solutions in healthcare, 45% said they were positive about the technology while 40% said that they had a negative view. The Commission has also recently launched a procedure to study the economic aspects of eHealth in general and of economic impact of interoperable electronic health records and ePrescription in particular.

### Commission Weighs up Options on eHealth Interoperability

The lack of interoperability in systems and services, such as electronic health records, patient summaries, and emergency data sets, has been identified as a major obstacle to the widespread take-up of eHealth applications in the EU. The Commission has launched a public consultation on the issue with a view to adopting specific guidelines.

The Commission's notion of e-Health interoperability is two-fold. In addition to the technical definition of the term that relates to connecting systems and exchanging information, it also seeks to recognise the concept of connecting people, data, and diverse health systems, while taking into account the relevant social, political, regulatory, business, industry and organisational factors.

### Plan Defines Priorities, Sets Agenda

The EU's e-Health action plan (2004) defines the block's priorities in the field

until 2010. One of them is the development of interoperable healthcare systems across the Union. In June 2006, the Commission's ICT for Health Unit adopted a new strategy to promote the transformation of the European healthcare landscape, in line with the Commission's new policy framework i2010. The Unit is currently in the process of drafting guidelines for good practice on eHealth interoperability.

According to the Commission, the ultimate goal of the recommendation is "to contribute to enabling the provision of a means for authorised healthcare professionals to gain managed access to essential health information about patients [such as the appropriate parts of a patient's electronic health record, patient summary and emergency data], subject to the patient's consent, and with full regard for data protection and security requirements" across Europe.

### Initial Information on Planned EU Action on Healthcare Services

The Commission is preparing its action on healthcare services and cross-border healthcare. In recent years these issues have been discussed widely at European level and the Commission has recognised the need to address current uncertainties about the application of Community law to health services, and to provide support for efforts to improve effectiveness, efficiency, quality

and safety of national health systems. Also health ministers have welcomed the Commission's initiative and endorsed the need for action. The planned EU action, which is to be tabled very shortly, is likely to be a package of legislative and non-legislative measures, a directive and a communication.

The Commission together with representatives from Member States is drawing up a list of highly specialised and expensive services, for which in case of a cross-border performance in a hospital a prior authorisation of the payment provider would be needed. For non-hospital care, no such authorisation would be required.

Also planned are extensive information rights for patients as well as the duty to inform from service providers and member states. The latter would have to set up "patient information centres", that would support patients from abroad to find the right service provider and in case of potential damage claims. ■



# ADVANTAGES OF THE WORLD'S FIRST DIRECT-CONVERSION FPD

## Making the Invisible Visible: SHIMADZU *safire* for Dynamic Cardiovascular Imaging

It is believed that direct-conversion FPD will revolutionise the world of cardiovascular and PCI imaging, and will be standardised in future-generation FPDs, since it allows proven advantages in image sharpness. It will not only achieve outstanding resolution for clinical images, but also offer the potential to reduce radiation and contrast injection, and increase safety, efficiency and clinical possibilities in your examinations. This article explores Shimadzu's *safire* for Dynamic Cardiovascular Imaging, launched as the world's first Direct-conversion FPD for Dual Application (Fluoroscopy & Radiography).

### Method

Fig.1 shows the x-ray conversion method for moving-image FPD. With indirect-conversion FPD, x-rays are first converted into light by a CsI phosphor, and this light is then converted to electric signals by photodiodes. During this process, light is scattered and images are made from those

scattered lights, making it impossible to achieve image quality equal to or better than that obtained with film. This conversion process and the phosphor material used are almost the same as that of I.I./CCD camera. So, the image quality is also expected to be the same as I.I./CCD.

On the other hand, direct-conversion FPD converts x-rays directly to electric signals. This method, while requiring an extremely high technical capability, is ideal for obtaining high-quality images.

Fig. 2 is a graph showing the modulation transfer function (MTF) for indirect-conversion FPD, direct-conversion FPD, film-screen, and the I.I. and CCD camera combination. The horizontal axis represents the spatial frequency and the vertical axis represents the transmission rate of image information. The closer the MTF is to 1.0, the more faithful the image is to the original. Direct-conversion FPD offers a spatial resolution that surpasses that of film-screen. On the other hand, indirect-conversion FPD offers only the same level of image quality as the I.I. and CCD camera combination.

Clinical images obtained by the Shimadzu Direct-conversion FPD *safire* systems in Fig. 3 shows a clinical image of the right coronary artery obtained by Shimadzu's Cardiac/Angiographic system. A stent implant along with its structure is very clearly visualised, objects which were difficult to observe with conventional I.I. or indirect FPD systems. The Shimadzu *safire* will greatly help your safe and prompt interventional procedures, and also mean that radiation exposure and injected contrast medium can be reduced, increasing patient safety by reducing risk.

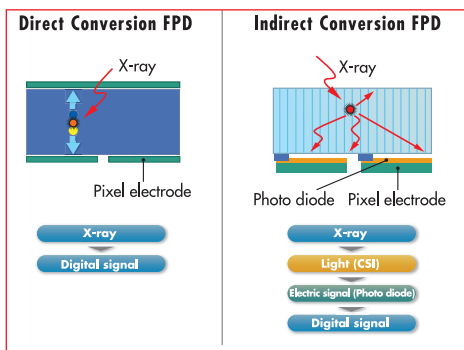


Fig. 1. X-ray Conversion Method for Moving Image FPD

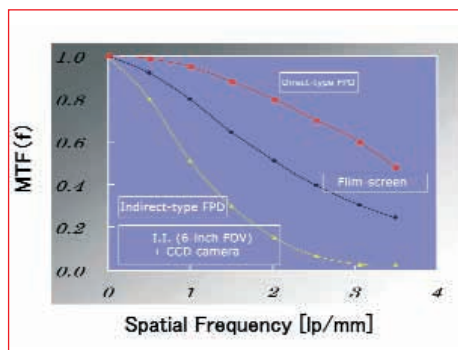


Fig. 2. Comparison of MTF Curve for Different X-ray Detectors



Fig. 3. Right Coronary Artery/Shimadzu Cardiac/Angiographic System



AUTHOR

**Prof. Lars Rydén**  
Cardiology Unit  
Department of Medicine  
Karolinska Institute  
Stockholm, Sweden

[lars.ryden@ki.se](mailto:lars.ryden@ki.se)

# ACCESS TO MEDICAL TECHNOLOGY DIFFERS ACROSS EUROPE

Survey Shows Variety of Causes for Discrepancies Between Guidelines and Practice

**The practice of cardiovascular medicine differs from country to country despite commonly accepted management guidelines. Discrepancies persist, even when comparisons are based on investigations of the proportion of patients with a defined disease offered a particular treatment modality.**

8

CARDIOLOGY MANAGEMENT

Surveys disclose that adherence to European guidelines for the management of different parts of cardiovascular practice may be unsatisfactory. Recent surveys show that prevention of people at high risk and those with previous cardiovascular disease manifestations is unsatisfactory across Europe.

Differences in educational standards may be one reason for discrepancies between guideline recommendations and practice. Other potential reasons may relate to traditions and cultural differences. Another clear cause for divergence relates to funding and reimbursement of cardiovascular practice and for making new medical technology, including drugs, available to patients and physicians.

## A Task Force Report

A task force within the framework of the ESC Cardiovascular Round Table gathered relevant information to study reimbursement as an obstacle to meeting recommended treatment standards. In the report, published in the European Heart Journal, attempts were made to study funding and reimbursement in

various European countries and to look at the transparency of the process of introducing new technology.

This editorial summarises the most important findings of the investigation, which was based on a review of existing European and national systems for healthcare funding and reimbursement and a questionnaire distributed to 47 national cardiology societies. Some recent experiences during the work with the European Heart Health Charter are included here.

## Funding of Healthcare

The amount of money spent across Europe on healthcare varies, as expressed by the percentage of the Gross Domestic Product (GDP). Funding for healthcare is mostly derived from public sources, taxation and/or social health insurance, and only to some extent from patient charges. Private health insurance is, in the vast majority of countries, only a small part of funding.

Countries within the EU may be grouped according to their sources of funding. One group receives funding predominantly from taxation; another from social

health insurance and a third uses a combination of tax and social health insurance. Sources and amounts of funding for healthcare vary significantly. The investigation did not permit a detailed analysis on how these different patterns influence patient access to medical technology, but it made it reasonable to assume that the different funding mechanisms play a potentially important role.

Thus, an increased demand from those insured, in one way or another, for the best possible return on direct or indirect investments may improve access to new medical technology. It seems less likely that such demands would improve inequity between countries. Still, increased public and medical professional awareness of the domestic reimbursement system and the amounts invested in the healthcare sector might be an important way towards better utilisation of available resources and to improve funding.

The reimbursement systems are, however, complex, underlining that not only individual physicians but also organisations representing the medical profession

should be actively engaged in these issues, something the questionnaire indicated not always to be the case.

### Reimbursement and Availability

The investigation revealed that the reimbursement system and available healthcare resources influenced the accessibility of medical technology. Equipment considered expensive, for example coronary stents and cardioverter defibrillators, were introduced earlier and more frequently in countries with a social health insurance system.

During the work with the European Heart Health Charter, meetings were held with representatives of the cardiovascular profession from all EU nations. There was a universal acceptance that prevention should be high on the future agenda of cardiovascular practice, but that it would be difficult to live up to the set standards.

### Prevention Not Satisfactorily Practiced

Recent surveys show that prevention is not satisfactorily practiced. When this discrepancy was discussed during the launch of the Charter it was repeatedly underlined that health insurance systems do not reimburse preventive efforts to the extent needed for a proper management of patients at high risk or with already manifest cardiovascular disease, promoting therapeutic rather than preventive activities.

Looking at the questionnaire, a majority of the national cardiac societies replied that reimbursement related factors limited the availability not only of new but also more established technology and that this related to drugs as well as devices.

Cost-constraints in combination with high patient co-payment were reasons mentioned. It may then seem surprising that less than half of these societies declared that they took an active part in reimbursement issues, mostly in an advi-

sory role and only rarely in lobbying. Moreover, few of them collaborated with the industry on this issue.

### The Role of Professional Organisations

The investigation indicates that knowledge on reimbursement systems is variable and not infrequently limited among the professional societies. Indeed, about half of national societies replied that they did not believe that funding or

tem based on patient needs, clinical evidence and practice guidelines.

### Concluding Remarks

It is likely that the involvement of the profession, perhaps best accomplished by activation of national cardiac societies, is mandatory for accomplishing an improved, more transparent system for making new medical technology, including drugs, available, that does not include inequity between countries.

“There is no isolated European solution to the problem with reimbursement”

reimbursement barriers limited the use of medical technology, an opinion not supported by the investigation.

Moreover it was a common opinion that medical devices are available as soon they have a CE mark. However, a CE marking does not take into account financial and economic constraints. The replies clearly indicate there is no isolated European solution to the problem with reimbursement and therefore availability.

Such issues have to be addressed at a national level and adapted to local conditions and constraints. In the future one would like to see a more consistent and transparent European reimbursement sys-

With regards to funding and reimbursement of medical technologies there is no single European model.

Each healthcare system has developed its own approach within the context of the cultural, political, economic and historical environments from which it evolved. Nevertheless each government clearly wants to maximise the health of its citizens and provide equitable access whilst at the same time controlling expenditure. It is this balance that needs to be considered and made fair and transparent. The concern that the economical system may be used to ration medical technologies that are useful and approved must be counteracted. ■



AUTHOR

**Dr. Giulia Cappellaro**  
Research Fellow  
Centre for Research on Health  
and Social Care Management  
Università Bocconi  
Milan, Italy

Member  
The European Health Technology  
Institute for Socio-Economic Research  
Brussels, Belgium

giulia.cappellaro@unibocconi.it

# ACCESS TO CARDIOVASCULAR TECHNOLOGY ACROSS EUROPE

The Role of Financing

Overcoming inequality in access to innovative technologies, while ensuring the long term financial sustainability of healthcare systems represents one of the strongest challenges for European governments. Discrepancies in resource allocation are still extant, on both health expenditure on GDP and on per capita spending on medical technology especially between Western and Eastern countries.

Homogenising access to cardiology services is of primary importance because it is the clinical area where innovation in medical technologies and practice can contribute the most to achieving life-saving gains.

## Cardiovascular Technologies: Main Determinants of Patient Access

Patient access to cardiology technology differs significantly across European countries. Implantation rates of implantable car-

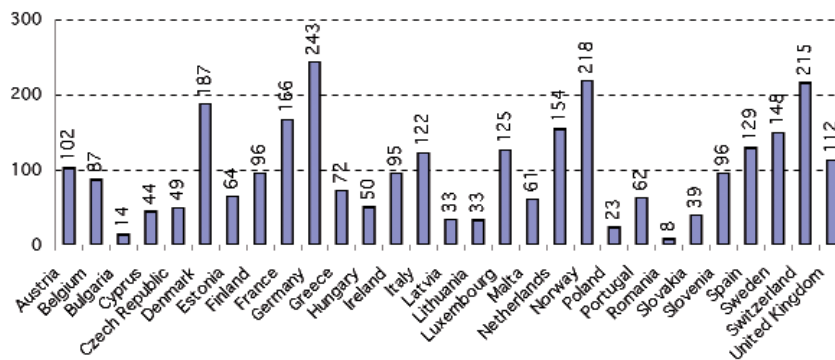
dioverter defibrillators (ICD), for instance, increased on average by more than 36% in the 2005 - 2007 period; nevertheless, in 2007 figures range from 232 implants/per million inhabitants (p.m.i.) in Germany to 53 implants p.m.i. in Greece (see graph 2). Variability in the current levels of technology utilisation can be determined by three macro-drivers:

(i) **Organisational drivers:** factors related to the availability of infrastructures and facilities (i.e. number of catheter labo-

ratories or emergency services per thousands inhabitants), as well as to the structure of the cardiac care delivery network (i.e. adoption of hub and spoke systems between providers in the area);

(ii) **Professional drivers:** factors related to medical profession (i.e. role of national cardiac societies in influencing the clinical practice);

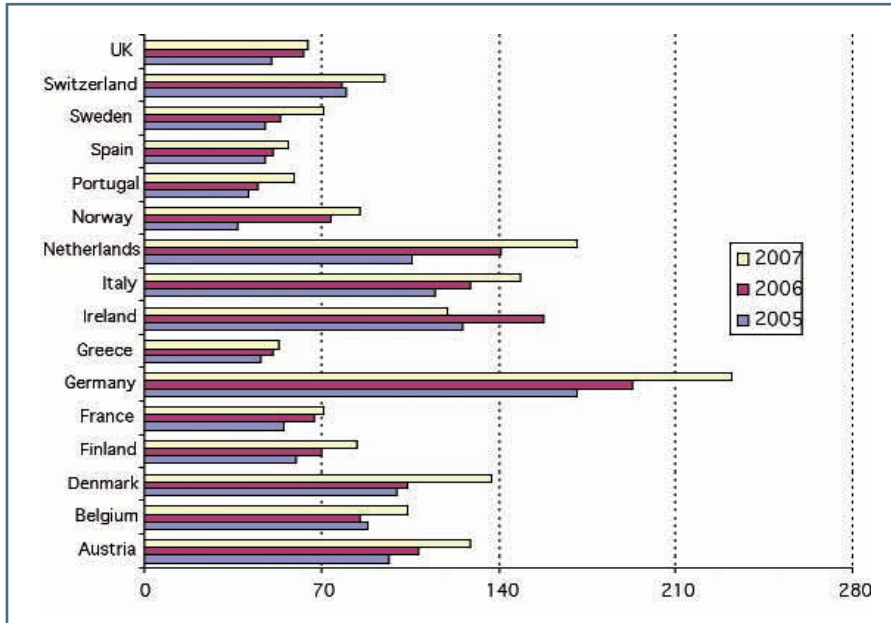
(iii) **Financing drivers:** factors related to the current country-specific financing structures of cardiovascular technologies.



Graph 1. Expenditure on Medical Technology Per Capita (Euro)  
Source: (Eucomed 2007)

The latter driver encompasses three dimensions equally, potentially influencing access levels to the same technology across European countries. These are:

1. Inclusion of the technology in the national benefit baskets or in the statutory insurance schemes and the degree of explicitness associated to its inclusion (coverage);
2. Financing arrangements between producers and providers (hospitals) regarding acquisition price, as defined by procurement mechanisms;
3. Financing arrangements between third



Graph 2. ICD Implant Rates Across EU Countries  
Source: (Eucomed 2008)

party payers (e.g. National and Regional Healthcare Authorities, Insurance Funds) and providers regarding the reimbursement mechanisms of the technology.

### Financing ICDs and Coronary Stents in the EU

Policy for financing medical technology (the third macro driver) differs both across countries and classes of device. An analysis of the mechanisms adopted by five countries - Germany, the UK, France, Italy and Spain - is presented here, with reference to ICDs and coronary stents.

#### Coverage

Each of these five European countries provides public coverage to the selected technologies; nevertheless, different degrees of explicitness characterise their inclusion in the official lists of health services guaranteed to citizens. Explicit listing is ensured by the Spanish (Real Decreto 1030/2006) and French regulations (Liste de Produits et Prestations Reimbursables - LPP) while in Italy and Germany it is rather the case-fee-payment system adopted for the reim-

bursement of inpatient services that indirectly defines the list of technologies included in the basket.

#### Procurement

Public tenders at single service provider level are the predominant purchasing mechanism for both technologies. Countries, nevertheless, register an increasing tendency towards the centralisation of procurement processes with the aim of leveraging economies of scale and increasing market power.

Hospital cooperatives have been established either at local (UK), regional (Italy and France) or transregional (Germany) level. With the consolidation of large top-down binding consortia, nevertheless, purchasing decision-making seems to focus predominantly on cost savings. This leads to a reduction of the input of clinicians and professionals, whose opinions are of paramount importance for the uptake of high tech life-saving devices. In Italy, moreover, explicit measures to regulate the offer were approved in 2007 with the introduction of national reference prices to be used as maximum ceil-

ings for future tenders; up till now, four categories of coronary stent have been identified, and corresponding prices range from 505 euros to 1,486 euros.

#### Reimbursement

Major differences between the five countries can be observed as to reimbursement regimes. Currently two main funding systems are applied: global budget and case-based schemes. Global budget schemes are predominant in Spain. A programme contract with explicit indication of the overall spending target is agreed upon annually between the Health Services of the Autonomous Communities and the hospitals on the basis of structural and complexity (case mix activity) elements (Sanchez-Martinez et al. 2006). Although in principle, the system may guarantee a higher degree of flexibility and total cost control, access to innovations is highly dependent on the criteria applied for budget determination. It becomes therefore essential not to rely exclusively on incremental adjustments of past allocations, but rather to strengthen other mechanisms of coordination and monitoring, such as internal commissions composed by both clinicians' and hospital managers' representatives, in order to ensure constant access and uptake of high quality technologies.

#### Discrepancies for Case-Based Schemes

Case-based schemes are well-established in Italy and Germany (Diagnosis Related Groups - DRGs) and recently adopted also in France (Groupes Homogène de Séjour - GHS) and the UK (Healthcare Resource Groups - HRGs). Hospitals are paid a tariff for each discharge, which should cover all the operating costs for ICDs/stent procedure.

Current funding arrangements deeply vary across the four countries, with reference to: **Classification coding:** All countries have introduced specific codes for both ICD and stent implant procedures, even though with different degrees of specifi-



cation; in particular, German classification appears to be the most analytical and regularly updated.

**Tariff setting and update:** In France and the UK the tariffs cover only the implant procedure, whereas devices are separately reimbursed through additional payments, either fixed at national level such as in France, or subject to local negotiations between commissioners and providers such as in the UK.

In Italy and Germany, by contrast, DRG tariffs are supposed to also cover the cost of the technologies implanted. Italy is nevertheless characterised by a high fragmentation between regions, in terms of introduction of supplementary fees on the top of the tariff (as in Lombardy or

Campania), or adoption of different fee schedules according to the type of device implanted (e.g. Drug Eluting Stents or Bare Metal Stents). In Germany, ad-hoc surcharges can be agreed at hospital level for two specific types of stents (coronary bifurcation stents and antibody-coated coronary stents), classified as innovative diagnostic and treatment methods (NUB).

**Control of the system:** Even though case-based systems have been introduced to promote efficiency, they might lead to cherry-picking of patients. Countries have therefore acted differently to guarantee equity of access and appropriateness of treatments for patients, for instance establishing independent valuation bodies (NICE in the UK or IQWiG in Germany).

### Conclusions

Coverage, procurement and reimbursement – the three components of a technology financing system – should not be considered as simple payment methods but rather as tools that, if properly regulated, can contribute to achieving higher degrees of equity in access to health services. Nevertheless, it is essential to reaffirm the importance of the other two drivers and, in particular, the professional dimension. Clinicians need to consolidate their role as stakeholders during all phases of the process.

This implies the need to invest in continuous training and education in order to not only to master their scientific field, but also to acquire managerial skills that will become essential to lead future healthcare organisations. ■



AUTHOR

**Manolis Karamalis**  
Reimbursement and Health Economics Director  
Medtronic International  
Tolochenaz, Switzerland

Acknowledgements:  
Gauri Bijur Saal (HealthEcon Write Ltd)

manolis.karamalis@medtronic.com

## OPTIMISING ACCESS TO CARDIOVASCULAR TECHNOLOGY IN EUROPE

### The Case For Device Implantation Rates

**Equitable access to healthcare forms one of the common objectives for EU Member States in the fight against social exclusion and poverty, yet barriers remain in the way of goals for optimum and homogenous access. For medical technologies, these barriers to access can be multi-factorial, yet broadly classified as stemming from the supply or demand side.**

In this article, within the focus of cardiovascular device implantation, we examine trends in the disproportions of access to innovative technologies and survey their possible influencing factors. Our objec-

tive is to briefly recapitulate findings from the literature on the prevalence of this problem in Europe to feed into policy discussions on optimisation and homogeneity of device implantation access.

### Variability and Inequality Despite Guidelines

Variability in the access to cardiovascular technologies has been observed to occur at many levels in Western Europe,

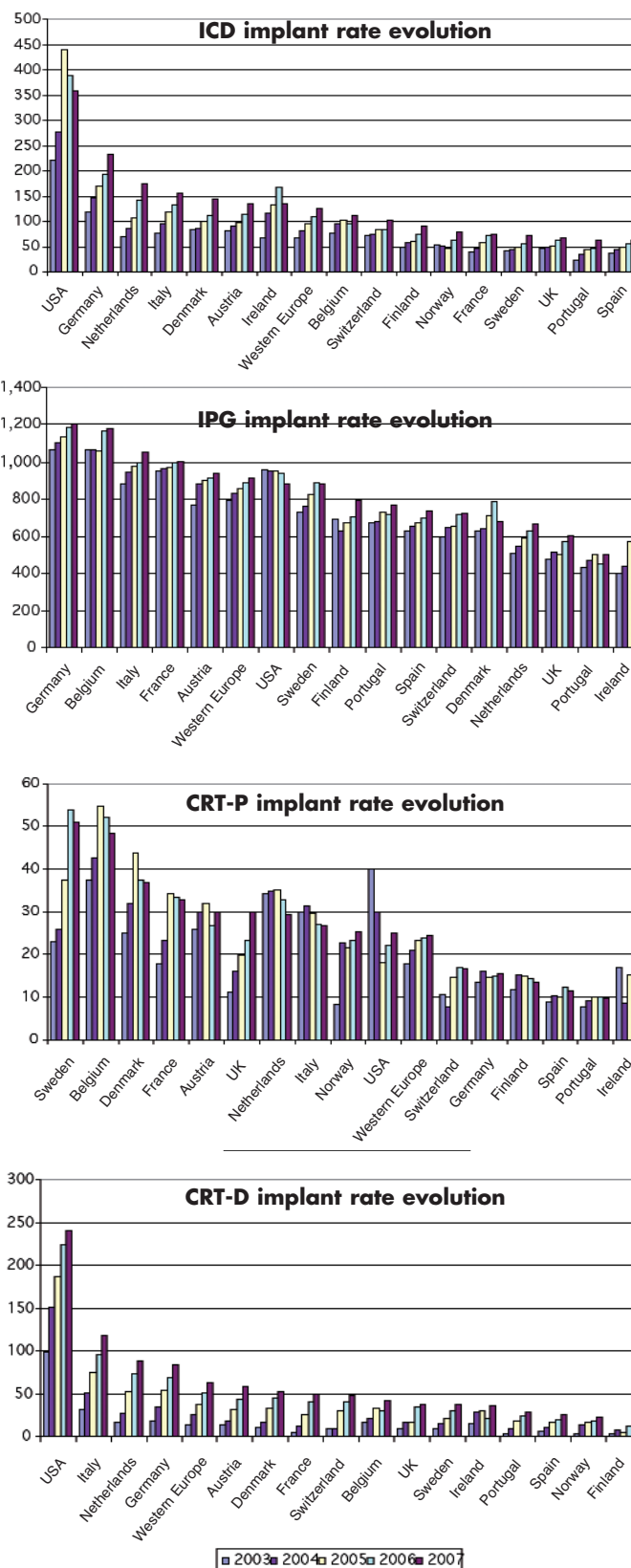
from international to local. For example, there is strong evidence indicating a high level of variability among Western European countries in the per-million utilisation of cardiovascular technologies despite commonly accepted management guidelines for their use. In contrast, disparities of access at local levels have also been measured within given regions.

Underutilisation forms another type of disparity when there are gaps between the true or projected incidence of need and actual rates of utilisation. When this occurs, the situation implies that not all patients within a local population with need for the technology are guaranteed access to it. Each of these situations in which unequal access occurs is surveyed in the current article.

### EUCOMED Data on Implant Rates Shows Disparities

On an international level, key data on cardiovascular device implant rates and trend comparisons between European countries and the US have recently been published by EUCOMED illustrating large disproportions in access patterns. These trends can be observed in the figures illustrating implantation rate evolutions. While an overall growth trend has been observed for all types of implants including ICDs, CRTs and IPGs across countries, actual implant rates per million patients have been shown to vary extensively with the exception of IPGs, for which there is less variability.

In this regard it has been noted that internationally recognised guidelines for pacemaker implantation and the dissemination of evidence-based findings have led to reduced differences between European and North American practices in the treatment of bradycardias and specifically by pacemakers. The same researchers propose that this variability may be underpinned by differences in the propor-





tion of GDP comprising healthcare expenditure, as well as discrepancies in the demographically-adjusted availability of practicing cardiologists and implant centres.

### Access Rates Tied to Wealth Not Disease Burden

Key studies in Europe on inter-region and inter-hospital variability have been led in Spain and the UK and confirm the existence of variability of access to cardiovascular technology for both diagnosis and treatment. Specifically in Spain, the use of coronary angiography is related to the wealth of the autonomous region, but not to the disease burden.

Other studies reveal disparities of cardiovascular device implant access and focus on numerous variables including supply, demand, regional wealth, and resources allocated to healthcare. Such work has shown that there is strong regional variability in the use of PCI, ICD and CRT, and that this variability is higher the more recently available the procedure.

For example, the ratio of variation between the maximum and minimum number of procedures done, ranges between almost double (1.95) for PCI, introduced in Spain in the 1980s, triple (3.04) for ICD, which became available in the 1990s, and above 15 (15.7) for CRT devices available at the end of the 1990s. Implant rates were also strongly associated with supply-driven variables including the number of centres that provided the procedure and the number of qualified implant specialists.

### UK Group Paints Alarming Picture for Cardiac Patients

In the UK, the Cardiac Network Device Survey Group has recently reported an alarming picture for cardiac patients in the NHS where it exposes major inequity of provision (“postcode prescribing”) between networks and primary care trusts for all classes of device and for pacemak-

er mode prescription. Furthermore, cardiac device implantation rates are amongst the lowest in Western Europe despite evidence refuting any difference in the prevalence of conditions for which implantation is indicated or the over-prescription of devices in other countries. The report also suggests some proposals to overcome these inequities:

- 1) Investment in implanting and follow-up services, and in education of health professionals at all levels of the referral chain to ensure that the ability to recognise, refer and act upon an indication for device implantation is optimised; and
- 2) The implementation of clinical pathways enabling the systematic identification and early assessment of potential candidates to improve the uptake of primary prevention device therapy.

Finally, underprovision of cardiovascular device implantation services has been cited in a number of recent studies conducted across Europe. These underprovisions, as based on the magnitude of gaps between incidence rates and actual implant rates, are normally estimated as a proportion of the actual number of procedures conducted compared to the number of indications in a population.

### Under-Provision of ICD Therapy in the UK

One recently conducted UK single-centre study observed significant under-provision of ICD therapy in the UK. This conclusion was based on an estimation of a combined projected ICD indication incidence (approximately 105 - 115/million/year) using published data for NICE secondary prevention indications as a benchmark and compared with the latest published UK ICD implantation rate data (of approximately 40/million/year). This significant level of under-use is comparable with other cardiovascular services in the UK, for

which the consequences have included higher morbidity and mortality rates. Separate studies in cardiovascular services in the UK have noted that constraints on costs were less likely to influence the decision to perform the procedure in a national health system as compared with a private healthcare market. Additional studies have also found strong correlation between ethnicity and access rates (adjusted for age, socio-economic status, and physician bias) with some ethnic groups less likely to receive cardiac procedures. Women also have been affected by age differences in cardiovascular management.

### Conclusions

At all levels the potential costs to societies are high from disparities in access to cardiovascular technologies; these disparities either manifesting as variability among populations or inequity within a population. The problem is an especially significant cause for concern in the cardiovascular indication given the enormous epidemiological burden of cardiovascular disease, its deadly health consequences and its high attendant costs.

Furthermore, the importance of homogeneity in the access to cardiovascular device implants such as CRTs, IPGs and ICDs is underscored by the incidence of sudden cardiac death which is a major health concern in developed countries, claiming more lives each year than stroke, lung and breast cancer, and AIDS combined. Given the potential these devices have in increasing patients’ chances of survival, policy discourse on healthcare equity must question the current patterns of device implant access, as revealed in numerous studies in the literature, and consider reallocation of resources supporting these innovative technologies. ■

References used in this article are available on request to the Editor at: [edi.torial@cardiologymanagement.eu](mailto:edi.torial@cardiologymanagement.eu)





AUTHOR

**Mr. Nikos Maniadakis**  
 Ass. Prof. Health Economics  
 & Management  
 Department of Economics  
 University of Piraeus  
 Piraeus, Greece

nmaniadakis@yahoo.com

# MARKET ACCESS IN EUROPEAN UNION COUNTRIES

## Pricing and Reimbursement of New Healthcare Technologies

A major aim of health policy in most EU member countries is to regulate and control the price of, access to and the use of new and expensive medical technology. Despite this common objective, there are great differences in the means used to achieve it, because healthcare, pricing and reimbursement systems as well as domestic industry and economic status and priorities are different across countries.

This article classifies and presents the common practices and mechanisms employed in different member states to determine access to and use of new pharmaceutical and medical technology. Practices either aim at the supply side or the demand side of the medical market.

### Supply-Side Practices

A commonly used measure is price control or regulation of medical technology. Prices may be set on the basis of production costs, the prices in other countries, of similar products within the country, the medical and economic benefits and the cost-

effectiveness of therapies under consideration. Another mechanism involves the direct control of healthcare expenditure where discounts, freezes, cuts and rebates are imposed on manufacturers. Often, agreements about price, volume and risk sharing are in place, where

	AT	BE	CY	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LV	MT	NL	NO	PL	PT	RO	SE	SK	SI	UJ
<b>Price regulation</b>																									
Price based on clinical data	•	•						•	•	•			•	•					•	•			•		
Price on economic evaluation	•	•						•	•	•			•	•						•	•		•	•	
Price on cost of existing treatments	•	•						•	•	•	•	•	•	•						•	•		•	•	
Price based on production cost								•	•																
Price based on international prices	•	•	•					•	•	•	•	•	•	•			•	•	•	•	•		•	•	•
Controlled price updates		•						•	•				•	•	•					•	•		•	•	•
Other	•				•				•											•	•		•	•	•
<b>Expenditure control</b>																									
Rebates and discounts	•			•				•	•		•	•	•								•				
Paybacks		•									•	•		•						•	•				•
Price volume agreements							•				•	•								•	•		•	•	
Price freezes and cuts		•						•	•	•	•		•	•					•	•			•	•	•
Other	•			•												•	•							•	•
<b>Industry regulation</b>																									
Profit control													•								•		•		•
Tax benefits		•						•			•									•	•		•		•
Other			•													•	•								•
<b>Reimbursement</b>																									
Reference price system		•		•	•	•	•	•			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Positive list	•		•		•	•			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Negative list				•					•	•									•						•
Economic evaluation	•	•			•	•			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Other															•					•				•	•

Table 1. Supply side measures  
 Source EC Report 2007



manufacturers pay back the state in cases where consumption is greater than a certain predefined level, or in cases where medical and economic benefits promised are not realised in real life. Other mechanisms involve the regulation and control of industry profit rates and tax obligations. Another group of measures involves the reimbursement policies applied. Often positive or negative lists, reference price systems and economic evaluations are employed to decide how to reimburse new pharmaceutical and medical technologies (see table 1).

### Demand Side Measures

Demand side measures focus mainly on changing the behaviour of the parties determining the demand for healthcare technology including physicians, pharmacists and patients. Physician measures include the implementation of practice and prescription guidelines, the implementation of education, the provision of information, the monitoring of prescribing patterns, prescription quotas, implementation of budgets and financial incentives, all of which influence their choices and market behaviour. In terms of patient measures the main one includes cost sharing, either in the form of fixed or variable co-payments, co-insurance or

deductibles. Lately, information and educational campaigns aim to guide and define patient behaviour. In terms of pharmacists, various incentives, schemes and discounts are used to promote substitution of expensive with cheaper drugs and technologies (see table 2).

### Direct Price Control

Price control is the easiest and oldest measure aiming to limit private and public pharmaceutical and medical technology expenditure to ensure the affordability of patient treatment and the financial sustainability of the healthcare system. Price control is common for instance in countries such as Austria, Finland, France, Italy, Ireland, Latvia, Lithuania, Poland, Slovenia and Spain. Evidence suggests that where prices are not controlled, they may be higher compared to countries where there is more regulation.

### Cost Sharing

Cost sharing is a commonly used approach to control access and expenditure even though it disproportionately affects low-income individuals. A form of splitting the cost of healthcare services in order to reduce public expenditure on the service, it aims to generate income or reduce expenditure for the third-party

payer, to reduce administrative costs, to make users cost-conscious, to promote competition, to reduce abuse and inefficiency and to facilitate access where needed. Countries where this approach is used include Austria, Italy, UK, Belgium, France, Greece, Estonia, Finland, Latvia, Lithuania, Poland, Portugal, Slovakia, Slovenia, Spain, Cyprus, Germany, Norway, Denmark, Sweden and Ireland.

### Reference Pricing

International price comparisons and reference pricing represent a new trend in EU countries. Price comparisons are used to set the price of the product in one country on the basis of other countries selected for this purpose. Reference pricing represents a mechanism for establishing a maximum level of third-party financing/reimbursement for a group of products classified somehow with a therapeutically equivalent class.

A price above the reference price is borne by the consumer to generate and reinforce price competition and to reduce cost especially when generic products become available, while maintaining standard quality. To be implemented, products are first clus-

Table 2. Demand Side Measures

	AT	BE	CY	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LV	MT	NL	NO	PL	PT	RO	SE	SK	SI	UJ
<b>Physicians</b>																									
Practice & prescription guidelines	•	•		•	•	•		•	•	•	•		•	•	•	•	•			•		•	•	•	•
Education and information	•	•		•	•	•		•	•	•		•	•					•	•	•	•	•	•	•	•
Monitoring prescribing	•	•		•	•		•	•	•	•	•	•	•				•	•		•	•	•	•	•	•
Prescription quotas		•		•				•							•			•							•
Predefined budgets								•							•						•	•			•
Financial incentives	•	•		•				•									•					•			•
Other						•														•					•
<b>Patients</b>																									
Information & education campaigns	•	•		•	•	•			•	•		•	•				•		•	•	•	•	•	•	•
Cost sharing	•	•		•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•
Other																•				•					
<b>Pharmacists</b>																									
Generic substitution			•	•	•			•	•	•	•		•		•	•	•	•	•	•	•	•	•	•	•
Financial incentives										•			•				•	•							•
Claw back	•	•											•				•		•						•
Other								•	•							•				•	•			•	•

tered in groups and then a formula is used to set the reference price.

### Risk-Sharing Mechanisms

Payback and risk-sharing mechanisms control access and expenditures on new therapies. In this context, manufacturers are asked to return a certain part of their revenue to a purchaser or the state authority if sales exceed a previously determined maximum amount or in cases where medical

ness and minimising risk and cost.

### Use of Generic Equivalents

Generic use promotion is a priority in many countries. Measures include fast track and cheaper registration of generics, encouraged or mandatory prescribing by active pharmaceutical ingredient, incentives for substitution in favour of generics by physicians and pharmacists and consumers, selective financing of generics in positive lists, reference

imposed in Cyprus, Denmark, Italy, Sweden, Finland, France, Hungary, Malta, Romania Slovakia, Slovenia and the Netherlands.

### Economic Evaluation

Finally, economic evaluation or otherwise cost-effectiveness analysis is also used in many countries either to set the price or the reimbursement level or to determine the prescription pattern of new technologies. This approach compares the extra cost and benefit of new products in relation to existing ones, to find out whether a fair premium is asked for the innovation. Nonetheless, it needs to be said that it raises issues as to what the threshold of fairness may be from one country to another.

### Conclusions

EU countries are all trying to promote greater and more equitable access to new medical and pharmaceutical therapies, but they also share common concerns about limiting public expenditure. The mix of measures employed is determined by their economic and industry status and by the characteristics of their health policy and health care system.

In this context direct price regulation, international price comparisons, economic evaluation, cost sharing, reference pricing, generic use, rational prescription and pay back policies are used in different ways to achieve the above often conflicting objectives. ■

# “Payback and risk-sharing mechanisms control access and expenditures on new therapies”

benefits have not been realised in real life either at individual or at population level. It is used in countries like the UK, Spain, France and Norway to reduce deviations from a prospectively set budget and to guarantee that a fair relationship will be attained between expenditure and benefit and to reduce the risk for the payer.

### Prescribing Incentives

Prescribing incentives involve the application of various explicit or implicit measures, which guide the choice and use of medical and pharmaceutical technology. The objectives tend to vary depending on the aims and priorities of those who establish them. Incentives are mainly aimed at maximising effective-

price systems, procurement by tendering, and favourable pricing policies. Obviously the main purpose of generic policies is to increase competition and access and to contain expenditure, without compromising quality and therapeutic equivalence.

Fast-track registration and/or lower registration fees are used in Austria, Finland, France, Hungary, Italy, the Netherlands, Portugal, Slovakia, and Sweden. Financial or other motives for doctors are provided in the UK, the Netherlands, Portugal, Romania, Italy and price control of generics is used in Austria, Cyprus, Finland, France, Hungary, Ireland, Italy, Portugal, and Slovenia. Generic substitution by the pharmacist is encouraged or

# THE CARDIOLOGY CARE CYCLE

## Revolutionising the Continuum of Cardiac Care

J. van den Hurk  
Arindam Mukherjee  
Philips Healthcare  
Best, the Netherlands

### What is the cardiology care cycle, and why do we need it?

The cardiology care cycle approach represents a paradigm shift in the provision of healthcare for patients at risk of cardiac disease. It covers all aspects of patient care from disease prevention to screening and diagnosis through treatment, health management and surveillance.

The cardiology care cycle also offers a useful tool for assessing care delivery, and identifying those areas where cost-effectiveness and quality of care might improve. For the industry, the cardiology care cycle helps to identify how the integration of products and services can create synergies that helps improve patient outcomes and reduce costs.

### Phases in Care Cycle Linked to Disease Development

The cardiac care cycle follows a number of different phases, described here. The different phases are closely linked to the development of disease. Primary prevention aims at inhibition of exposure to risk factors and usually targets the entire population or groups that are at risk of developing cardiac disease. Health promotion, health education and health protection are three main aspects of primary prevention.

Secondary prevention is targeted at asymptomatic individuals at risk in order to prevent or delay onset of the disease. Secondary prevention strategies include screening activities and prophylactic treatment. The onset of symptoms marks the

transition to clinical disease. The next phases of the care cycle are diagnosis, treatment, management and surveillance, and apply to individuals with the clinical disease.

The purpose of these phases is to prevent further impact from the disease by relieving the effects of the disease (e.g. by angioplasty or surgery), retarding further progress of the disease, and tertiary prevention (i.e. prevention of disease recurrence). Depending on the severity of the disease, care may include chronic treatment and surveillance.

### Philips Simplify Cardiac Care

At Philips, Simplifying Cardiac Care through the care cycle approach has led us to focus on four main cardiac themes

- Timely triage;
- Discovery to treatment;
- Minimally invasive interventions, and
- Home healthcare.

By examining one of these main cardiac themes, the benefits of the care cycle can clearly be seen

### Discovery to Treatment Approach Enables Better Resource Utilisation

The care cycle approach helps reduce time to treatment for heart attack patients. The Philips "Discovery to Treatment" approach helps reduce "Door to Balloon" time to below 90 minutes. This approach allows hospitals to better organise resources before patients enter their doors; and more crucially, saves more lives.

The Philips "Discovery to Treatment" approach enables physicians to treat cardiac arrest patients more effectively right from the point of discovery. New systems allow paramedics to immediately transmit data from ambulance to hospital; in turn, clinicians in hospitals can receive ECG data and assess a patient's condition and the type of treatment they need before the patient arrives at the emergency department.

When a patient suffers a heart attack, heart muscle starts dying immediately and every second saved between onset of chest pains and administration of treatment is vital. It is proven that reducing the time from discovery to treatment has a significant impact on a patient's long-term recovery. Experts recommend that those suffering from the most common and deadly form of heart attack receive treatment within 90 minutes to reduce damage to heart muscle.

### Philips provides effective solutions for savings lives

The new "Discovery to Treatment" solution offered by Philips comprises a combination of products:

- HeartStart MRx Monitor/Defibrillator,
- Tracemaster Vue ECG management system,
- Intellivue patient monitoring,
- Xper CathLab FD10, and
- CVIS (cardiovascular IT management system)

The HeartStart MRx monitor/defibrillator enables paramedics to wirelessly trans-



“With over 17 million people around the world dying from cardiovascular diseases each year, such diseases are the world’s number one cause of death. That’s why we’re working together with cardiologists to develop technologies that integrate into each part of the cardiac care cycle – from emergency care to diagnosis, treatment and long-term care.”

mit vital 12-lead electrocardiogram (ECG) patient data on the heart’s condition while en route to the hospital along with the patient. Once this data is received, the Philips Tracemaster Vue system manages the ECG data and the care givers move into action, preparing the Catherization (Cath) lab Xper FD10 before the patient arrives. Upon arrival of the patient at the hospital, all usual administration is by-passed because all details pertaining to the patient have been already received and entered in the system.

The patient’s vital signs are continually monitored now using the Philips Intellivue monitor which accompanies the patient

through the hospital. From the traveling ambulance to the emergency room to the Catherization (Cath) Lab, clinicians can make early assessments that would usually be made after arrival at the

hospital. This significantly speeds up heart attack treatment.

#### Delivering Seamless Information Sharing

Philips Cardiovascular information solutions (CVIS) throughout the discovery to treatment care cycle delivers instant access to the seamless sharing of clinical information throughout the hospital. Inside the emergency department and the cath lab, Philips cardiovascular imaging equipment helps clinicians confidently plan and execute interventional procedures.

As a patient moves through the continuum of cardiac care and receives care in the ambulance, emergency department, diagnostic imaging centre, cath lab, operating room and/or critical care ward, Philips helps to manage the flow of patient information, making it available when and where it is needed to enable care providers to offer better, faster care. Philips is uniquely positioned to help customers in each of the settings as well as the home.

# PHILIPS

For more information please visit  
[www.healthcare.philips.com/cardiology](http://www.healthcare.philips.com/cardiology)



#### AUTHORS

**Dr. Leonie Ruhmann**  
**Prof. Mathias Goyen**  
UKE Consult und  
Management GmbH  
Hamburg, Germany

goyen@uke.de

## MARKETING YOUR HEALTHCARE SERVICES

**Healthcare's once-upon-a-time days are gone. Simply being the nearby hospital does not automatically stake your organisation's financial claim. So, in an increasingly competitive industry, what is the ideal way to market a hospital or healthcare service to consumers—who are often no longer just patients?**

Throughout Europe, healthcare has to date remained largely insulated from normal market mechanisms. Rather, healthcare providers are operating in a jungle of rules and regulations created by bureaucrats and enacted by politicians. Obviously, there are many reasons why healthcare cannot be considered a “normal market”. First and foremost, health is a very special commodity which should be affordable for all members of a society regardless of their income levels. Acceptance of this paradigm remains the basis for all European healthcare systems. Despite the introduction of patient co-payments for physician visits as well as medication, thankfully there appears to be consensus that healthcare needs to remain available for all in need.

Insulation from market mechanisms has resulted in highly inefficient healthcare service structures. Ever-increasing healthcare costs have now resulted in a growing trend towards the introduction

of market mechanisms based on supply and demand. In some regions, particularly large metropolitan areas, healthcare providers are therefore confronted with increasing competition mandating the development of marketing and sales strategies for individual healthcare providers.

#### Take home points:

- Current health systems based on state-governed regulations have failed to provide affordable and efficient health care.
- The introduction of market mechanisms based on supply and demand to healthcare is rapidly gaining acceptance.

#### Healthcare - a Special Product

In an abstract sense, healthcare is a product rather different from most other commodities. From a customer perspective it is of unsurpassed value, as it represents the virtual bases for a productive life. Despite its importance to

the individual patient, it is difficult for the customer, i.e. the patient, to define its monetary value or the required product quality. Healthcare providers expect their patients to trust that their product is of high quality and priced correctly. In view of the multitude of regulations governing the way healthcare is provided, patients only too willingly place this trust into health care providers and their professionals including physicians, nurses and technologists.

Unfortunately, relying on rules and regulations does not necessarily assure sufficient quality of healthcare. In contrast to all other products, regulations governing the health sector only affect the process of administering healthcare regardless of outcome. If the same principles were applied to the production of cars, the assembly of brakes in a car would be regulated whereas performance of the same brakes would not be subject to any checks at all.

Increasingly, patients are becoming aware of this central shortcoming of European healthcare systems. The pressure has grown to a point where even governments are reacting. New rules and regulations are being implemented. Most again fall short of what is needed: transparency of quality and pricing for healthcare products to the customer, i.e. the patient. Efforts to provide reliable quality data can hence be considered one of the most important contributions to any health marketing strategy.

The process of pricing healthcare products has remained as elusive to the average patient as the assessment of product quality. For many healthcare services, patients do not even receive a bill. Rather, payments are provided by anonymous insurance or health service agencies in accordance to rules lacking in transparency and frequently sense. For the healthcare market to gain in efficiency, it is of utmost importance that pricing becomes transparent to the patient. Clearly this does not mean that bills should also be directly paid by the patient. Rather, the underlying insurance system with acceptable co-payments should be maintained.

Take home points:

- For market mechanisms to unfold their desirable effects, healthcare products must become far more transparent to the customer, i.e. the patient, regarding pricing and quality. The latter should be based on outcome and should represent a central theme in all marketing strategies.
- While transparency in pricing requires patients to be billed, it does not require the patient to pay those bills themselves. Rather, the underlying risk sharing systems should be maintained as payers.

### Hospital Marketing Strategy

Just like in other industries, marketing a

hospital or healthcare system comes down to brand awareness. If your hospital's name is well-regarded within the community and by potential patients, you have a distinct advantage over competitors.

Most healthcare professionals would probably associate marketing with advertisement strategies. First and foremost, such strategies should focus on information to the patient. Transparency should be provided regarding the quality of the medical products offered. The creation of an attractive and content-rich internet platform clearly represents a cornerstone in this undertaking. Furthermore, occasional press releases documenting the success of medical treatments should be prepared and distributed into all available channels. Finally, advertisement strategies can also include direct marketing measures such as letters to treated patients outlining progress in diagnosis and therapy regarding their disease. The healthcare provider should be careful however to respect all laws and regulations governing advertisement in the healthcare sector in most European countries. Marketing, however, covers far more ground than mere 'advertisement'. In a sense, marketing represents the very core of any company by first and foremost defining a product portfolio.

Hence we can summarise as follows: the central aspect of any marketing concept relates to the definition of products. Advertisement strategies only represent the tail end of a marketing concept.

### Product Portfolio

In our current hospital world, product portfolios have by large developed in a historic sense. While there are variations in the number and type of healthcare products offered by different hospitals, few providers have consciously decided

upon what is offered as part of the existent product portfolio. Rather, portfolios appear to be the results of historic processes based on individual physicians' interests and abilities as well as perceived patient needs, expressed by insurance carriers. Frequently, a hospital offers various healthcare products for no identifiable reason at all.

As a first step in the process of developing any marketing strategy, the currently offered products should be listed. Using portfolio analysis tools each of these products should be analysed regarding quality, profitability, and future relevance. The assessment of quality and profitability should be based on comparative benchmarking data. Both factors generally relate to volume.

Thus, there is ample data illustrating a direct relationship between outcome quality of a particular procedure or operation and the number of times that this procedure is performed within the same hospital in a given time frame. Case volume has also emerged as a direct predictor for cost. Similar to most other products, economy-of-scale effects contribute toward reduced cost also of medical procedures. Put differently: the same procedure becomes less expensive if it is performed more often within the same hospital.

Take home points:

Product portfolios should be consciously defined based on different criteria including quality, cost and 'future relevance'.

### Unique Selling Proposals (USPs)

Future relevance of products relates to existent Unique Selling Proposals (USPs) of the hospital offering the product. Each hospital should define these USPs which set it apart from its most direct competitors. USPs can

*continued on page 44*

# CARDIAC CT

## A Snapshot of Coming Developments



AUTHOR

**Jason Launders**  
Analyst  
ECRI Institute  
Pennsylvania, US

jlaunders@ecri.org

The primary reason for the development of cardiac CT was the expectation that CT could replace diagnostic cardiac catheterisation procedures, an expensive study that, due to the need for arterial catheterisation, has a relatively high complication rate. But where will this relatively new technology go, and how will it improve imaging techniques for cardiologists? This article explores the issues involved.

4-slice CT systems enabled calcium scoring, which is used in cardiac risk assessment, and gave a glimpse of the potential for assessing the coronary arteries using CT angiography (CTA). 16-slice systems delivered negative predictive values comparable to conventional cardiac catheterisation (i.e., ability to safely rule out the disease), though the selection criteria for patients were exacting. A number of studies have compared 64-slice CT to the gold standard of cardiac catheterisation, including those summarised in table 1 (see below). When the data is combined, the sensitiv-

ity of 64-slice CT is about 92% and specificity 96%. Most importantly, the negative predictive value is 98%. In other words, if a patient has a negative scan, there is a high degree of certainty that the patient can be safely discharged.

### Radiation Dose for Cardiac Studies a Concern

However, radiation dose for cardiac studies is a significant concern. CT is well recognised as delivering a high radiation dose to patients and cardiac CT is one of the highest dose CT exams, due to the

need to overlap slices to ensure sufficient raw data is acquired. Cardiac catheterisation also incurs a high radiation dose. The issue is that CT will be used with patients with a lower pre-scan probability of coronary artery disease. As a result, the justifiable dose is lower. All CT manufacturers have made significant progress in lowering the radiation dose by reducing the amount of wasted x-ray exposure. For example, using axial image acquisition instead of spiral acquisition or applying more aggressive ECG gating techniques can significantly reduce the dose.

### New Developments

CT technology has not stopped with 64-slice systems. In 2005, Siemens Medical Solutions introduced the dual source CT system (Somatom Definition) that halved the temporal resolution. Temporal resolution is the key factor in cardiac imaging since it determines the heart rates that can be effectively imaged without resorting to heart rate control medication.

In a normal CT system, the highest possible temporal resolution is half the gantry rotation time. By adding a second source and detector the temporal resolution is reduced to one quarter the

Reference	Number of Patients	True Positives (TP)	False Positives (FP)	True Negatives (TN)	False Negatives (FN)
Ehara et al., 2006	69	275	35	545	29
Leschka et al., 2005	67	165	25	804	11
Pugliese et al., 2006	35	66	19	408	1
Raff et al., 2005	70	79	41	802	13

Table 1. Selection of studies comparing 64-slice CT and cardiac catheterisation for the detection of coronary artery stenosis.



rotation time. Testing with dynamic phantoms shown by ECRI Institute (May 2008) show that heart rates up to 85 bpm and variable heart rates can be successfully imaged. For comparison, normal 64-slice systems are typically limited to 65 bpm and stable heart rates. By removing the need for medication, patient scheduling becomes easier

## “CT may become a one-stop shop tool for cardiac risk assessment”

and the need to monitor patients before and after the scan is reduced.

Other developments are also now becoming commercial realities. Most notably is a 320-slice system (Aquilion One, Toshiba Medical), which acquires 16cm long volumes in each rotation. So, the whole heart can be acquired in a single rotation. In any other CT scanner it is necessary to make multiple rotations and select the best data after the scan. A necessary assumption is that the heart returns to exactly the same position for each cycle. With the 320-slice system, this is no longer a problem. So, smaller vessels should be better visualised. Other manufacturers are also working on extending the coverage.

There is more to cardiac imaging than the coronary arteries. CT is also now being used for myocardial perfusion imaging, quantitative assessment of the ventricular output, and plaque characterisation. It is early days but results are promising. It may be that CT will become a one-stop shop tool for cardiac risk assessment. However, dose concerns and over utilisation of the technology are issues that must be addressed.

### Patient Demand and Utilisation

The common early expectation was that demand for coronary CTA would be overwhelming and cardiac CT would rapidly become a major source of patients and revenue. However, anecdotally it appears that the number of exams remains low (e.g., Dowie, 2007). Why the slower than expected utilisation?

There are probably many reasons, including physician competence and credentialing requirements, staff training, referral practices, appropriate indications, and reimbursement.

The appropriate indications and reimbursement issues are closely linked and subject to considerable debate and confusion. In 2006, a multidisciplinary clinical committee in the US published a report that summarised their conclusions regarding the appropriate indications for coronary CTA that are supported by evidence (Hendel et al. 2006). A number of indications were found to be appropriate, including the evaluation of some intermediate risk patients with acute chest pain, such as would present to emergency rooms.

### Will Coronary CTA Replace Nuclear Stress Test?

A significant related question is whether a coronary CTA is a suitable replacement for a nuclear stress test. The 2006 appropriateness criteria (Hendel et al., 2006) specify that only patients with equivocal stress tests or those unable to exercise (i.e., can't complete a stress test), are suitable

candidates for coronary CTA. The nuclear stress test is routinely performed on low and intermediate risk patients that present with chest pain by the cardiologist. A nuclear stress test is a physiological study that identifies regions of the myocardium that receive inadequate blood flow during exercise, usually caused by significant arterial stenosis.

In contrast, coronary CTA detects arterial stenosis that may or may not be significant. Supporters of the stress test point out that the physiological nature of the stress test provides more relevant diagnostic information. Despite this difference, a recently published direct comparison of the imaging techniques shows similar diagnostic accuracy (Gallagher et al., 2007). So, for the time being, the nuclear stress test remains the primary option. However, coronary CTA may replace nuclear stress test in the future.

### Insurance Companies Reluctant to Expand Indications

There is considerable pressure, particularly from radiologists, to expand the indications for coronary CTA. However, insurance companies are reluctant to change their policies despite coronary CTA being about the same cost as a nuclear stress test. Possible reasons for not changing the referral policies include the concern that utilisation may be less controllable and the high number of incidental findings may increase costs of follow-up diagnostic tests. So overall, costs would increase. In addition, cardiologists would lose patients undergoing stress studies, which they usually conduct and are reimbursed for. The bottom line is that economic and political issues are likely to be important factors in this debate and uncertainty over reimbursement remains controversial. ■

*References and further recommended reading lists are available upon request to the Editor at [edi.torial@cardiologymanagement.eu](mailto:edi.torial@cardiologymanagement.eu)*



INTERVIEWEE

**Prof. Gilles De Keulenaer**  
 Cardiologist  
 University of Antwerp  
 Cardiovascular Centre  
 Antwerp Middelheim  
 Antwerp, Belgium

gilles.dekeulenaer@ua.ac.be

## SETTING UP A HEART FAILURE CLINIC

Ensuring Operational Efficiency

### Why was it decided to set up a heart failure clinic at the UZ Middelheim?

This hospital is a university affiliated facility with a large interventional cardiovascular programme of more than 4,000 diagnostic coronary angiograms, and more than 2,000 PCIs per year. Over the years, improved prognosis of acute coronary syndromes has led to an increased burden of chronic heart failure. The older age of the heart failure population, their co-morbidities and the rapidly evolving therapeutic opportunities in heart failure have urged to add a specialised programme of ambulant care in the cardiovascular division. Cardiac rehabilitation, organised optimisation of medical therapy, and evidence-based selection for “advanced device therapies” were the pre-defined goals of this heart failure clinic.

### Please describe the activities of the centre.

The centre combines a heart failure clinic and cardiac rehabilitation centre, situated

on the ground floor of the hospital. The multidisciplinary para-medical team includes physiotherapists, a psychologist, a social nurse, a dietician, and a heart failure nurse and is led by two non-interventional cardiologists. Apart from a large fitness room, the centre has room for “semi-open-door” ambulatory patient visits, echo-Doppler imaging, and cardio-pulmonary exercise testing. The “semi-open door” service provides medical consultation by appointment, and guarantees consultation within 24 hours in case of increased com-

plaints. A heart failure nurse can be reached by telephone daily from 8 AM - 4 PM. Serum analyses are performed one hour before a patient’s visit, with results available during the consultation. Heart failure teaching is given by the heart failure nurse. Yearly, about 1,500 ambulatory heart failure visits are performed. A quarter of these visits consist of a combined assessment by cardiologist and nephrologist allowing dual analysis of patients with combined heart and kidney failure. In parallel with this, more than 400 patients per year complete a 4 - 6 month cardiac rehabilitation programme.

### How was the project budgeted for, and how is it funded?

The clinic’s multidisciplinary team is funded by the profits from the cardiac rehabilitation activities, although this does not cover the whole budget. Most multidisciplinary heart failure clinics, therefore, are part of a larger “tertiary” cardiovascular division. This is not an ideal situation, since there is a greater need for heart failure clinics than tertiary cardiovascular divisions.

“Improved prognosis has led to an increased burden of chronic heart failure”

### How did you decide to assign roles within the centre? Were there any issues in dividing up work for nurses, physicians, etc.?

Some heart failure clinics in other countries are “nurse-led”, but ours is physician-led as nurses in Belgium are not allowed to take final medical responsibility. The heart failure nurse promotes accessibility, should enjoy the patient’s confidence, teaches them how to live with heart failure, and is the first person to contact in case of problems or questions. Medical decisions are always made or

approved by the heart failure cardiologist. Despite this, a heart failure nurse is a “sine qua non” to organise a heart failure clinic. The heart failure nurse increases accessibility to the clinic, has a central position in recruiting patients from the ward to the clinic, provides in- and out-hospital heart failure teaching.

### How are referrals made to the centre?

Most patients in the clinic have been referred following hospitalisation for

and a multidisciplinary team;

- To find space for the clinic in the hospital, that is easily accessible for older patients and,
- To convince colleagues that advanced heart failure patients should be followed in a heart failure clinic, rather than in a private practice.

Once started, the last one is the toughest. Patients with heart failure usually have a long cardiological history and often have been followed throughout outside the heart failure clinic before.

## “Motivate your patients for cardiac rehabilitation... it can drastically improve their quality of life.”

acute heart failure. Thus, our patients have more advanced disease, and are at high risk for re-hospitalisation. During follow-up of these patients, we carefully respect written communication with the primary care physician by sending clinical reports immediately following an ambulatory visit. Also, patients receive a heart failure diary, in which body parameters like blood pressure, body weight, and medication can be noted by patient and care provider.

### What were your most significant challenges ?

The three most important hurdles were:

- To convince colleagues within the division to invest in a heart failure nurse

Long-standing physician-patient relationships are not given up easily.

### How do you ensure that you are working in tandem with primary care physicians?

Since our heart failure population has advanced disease, often with co-morbidities like kidney failure, primary care physicians do not feel threatened. Most primary care physicians are reluctant to change medications once heart failure is advanced, devices are implanted or kidney failure is present. Also, the number of patients with advanced heart failure per primary care physician represents only a fraction of their total clientele. They don't mind

that these patients, often with poor life expectancy, receive specialised and advanced care.

### What is your advice to other heart failure clinic directors?

1. Provide post-hospitalisation visits within two weeks of discharge. Re-hospitalisation rates are highest then, and often medications need adjustment because of hypotension, fluid imbalances, etc.
2. Find a well-trained and dedicated heart failure nurse to build a relationship of trust with patients and to offer daily telephone assistance. She will absorb many smaller problems at an early stage before things escalate.
3. Collaborate with a nephrologist that has a feeling for haemodynamics.
4. Motivate your patients for cardiac rehabilitation. It can drastically improve your patient's quality of life.

### How do you manage patient data? What sort of IT infrastructure is in operation?

We keep electronic files, making them permanently visible and accessible to all medical providers in the hospital. Currently, we are involved in a project that provides website-based files, and in which brief notes by general practitioners and the heart failure clinic can be left – an elegant way of communication. When this approach is combined with telemonitoring of heart failure symptoms and some physiological parameters, that trigger warning emails to GP and clinic when abnormal, a true interdisciplinary collaboration arises that has a good chance to reduce unnecessary hospitalisations. ■



AUTHOR

**Prof. Alexander G.G. Turpie**  
 Department of Medicine  
 Hamilton Health Sciences  
 Corporation  
 Ontario, Canada

turpie@mcmaster.ca

## RECENT DEVELOPMENTS IN ANTICOAGULATION

### Implications for Management of Cardiovascular Conditions

Anticoagulants are recommended for a wide variety of indications, including the prevention of venous thromboembolism (VTE; comprising deep vein thrombosis [DVT] and pulmonary embolism [PE]), the treatment of VTE, stroke prevention in patients with atrial fibrillation (AF) and secondary prevention of major ischaemic outcomes in patients with acute coronary syndrome (ACS). This article sums up the recent developments in anticoagulants and discusses the implications for the management of cardiovascular conditions.

Established anticoagulants include unfractionated and low molecular weight heparins (UFHs and LMWHs), vitamin K antagonists (VKAs) and, more recently,

the synthetic pentasaccharide fondaparinux (see table 1). Until recently VKAs, including warfarin, were the only approved oral anticoagulants but they

have a narrow therapeutic window, require routine laboratory monitoring and have multiple food and drug interactions. The development of novel antico-

Property	Vitamin K antagonists	Unfractionated heparin	LMWH	Fondaparinux	Dabigatran	Apixaban	Rivaroxaban
Target	Vitamin K-dependent clotting factors	Multiple	Multiple	Indirect Factor Xa	Direct Factor IIa	Direct Factor Xa	Direct Factor Xa
Administration	Oral	Subcutaneous	Subcutaneous	Subcutaneous	Oral	Oral	Oral
Prodrug	No	No	No	No	Yes	No	No
Dosing†	Once daily INR-adjusted	2–3 times daily	1–2 times daily	Once daily	1–2 times daily	Twice daily	Once daily
Onset of action	72–96 hrs	20–60 minutes	2 hrs	2 hrs	2 hrs	3 hrs	2–4 hrs
Bioavailability by route of administration	100%	Variable	80–90%	100%	6.5%	>50%	>80%
Half-life	36–42 hours	Dose dependent 1–1.5 hours in vitro	4–7 hours	17 hours	14–17 hours	9–14 hours	5–9 hours 11–13 in elderly
Antidote	Vitamin K produces slow reversal	Protamine sulphate	Partially neutralized by protamine sulphate	None	None	None	None
Mode of elimination	Renal	Renal, reticuloendothelial	Renal	Renal	Renal (80%)	Renal (25%), hepatic (75%)	Renal (66%), hepatic (28%)
Monitoring	Yes	Yes	No	No	No	No	No
Drug interactions	Multiple	Other anticoagulants, antiplatelets and thrombolytics	None relevant known	None relevant known	Proton pump inhibitors	CYP3A4 inhibitors and P-glycoprotein inhibitors	CYP3A4 inhibitors and P-glycoprotein inhibitors

Table 1. Properties of established and new oral anticoagulants\*

\*Compiled with data from Stangier et al. 2007, Gross and Weitz 2008, Haas 2008, Kubitza et al. 2005, Weinz et al. 2004; Ansell et al 2008; †may vary with indication. INR, international normalised ratio; LMWH, low molecular weight heparin.

agulants has focussed on small molecules that target only one coagulation factor specific for the final common pathway in the coagulation cascade.

### New Anticoagulants

At present, there is one orally administered direct thrombin inhibitor (DTI) available on the market, dabigatran, launched in Europe and Canada for the prevention of VTE in adult patients who have undergone elective total hip and knee replacement (THR and TKR) surgery. It is under investigation for VTE treatment, and prevention of cardioembolic events in patients with chronic AF. Other agents, such as AZD0837 and direct FXa inhibitors are also in development. Proof of concept for targeted FXa inhibition, was provided by fondaparinux, although this agent requires parenteral administration.

### Dabigatran

#### Pharmacology

Dabigatran etexilate is an orally available prodrug that is converted rapidly to its active form dabigatran. It is a potent, competitive and reversible DTI.

#### Clinical trials

In the RE-NOVATE and RE-MODEL studies, dabigatran 150 mg and 220 mg were both non-inferior to enoxaparin 40 mg once daily for the prevention of VTE in adults undergoing elective THR and TKR, respectively. Dabigatran had a similar safety profile to enoxaparin in both trials. The RE-MOBILIZE trial compared dabigatran with the North American enoxaparin regimen (30 mg twice daily) for the prevention of VTE after TKR. Dabigatran failed to demonstrate non-inferiority to the twice-daily enoxaparin regimen.

The clinical trial programme also includes studies of dabigatran in treatment of acute DVT and PE (RECOVER), prolonged prevention of recurrent VTE (RE-MEDY and RE-SONATE) and the prevention of stroke and systemic embolism in patients with AF (RE-LY). The RE-DEEM study will evaluate safety and indicators of efficacy with four doses of orally administered dabigatran etexilate in ACS patients who have had a myocardial infarction, and are therefore at high risk for further cardiovascular events.

### Apixaban

#### Pharmacology

Apixaban is an oral, highly selective, direct inhibitor of free and prothrombinase-bound FXa.

#### Clinical trials

Three large phase III studies are evaluating the safety and efficacy of oral apixaban in patients undergoing elective TKR (ADVANCE-1 and -2) and THR (ADVANCE-3). Results of ADVANCE-1 indicated that the rate of the primary endpoint of this study was numerically similar to that observed with enoxaparin (9.0% vs 8.9%,  $p=0.064$ ), but did not meet the pre-specified statistical criteria for non-inferiority compared with the US dosing regimen of enoxaparin.

The apixaban clinical trial programme is also investigating apixaban for VTE prevention in medically ill patients (ADOPT), VTE treatment (AMPLIFY and AMPLIFY-EXT) and stroke prevention in AF (ARISTOTLE and AVERROES). A phase II, randomised, double-blind, placebo-controlled, multi-centre clinical trial (APPRAISE-1) to assess the

*continued on page 45*

	Total hip replacement surgery				Total knee replacement surgery	
	RECORD1		RECORD2		RECORD3	
	Enoxaparin	Rivaroxaban	Enoxaparin	Rivaroxaban	Enoxaparin	Rivaroxaban
Total VTE n (%)	58/1,558 (3.7%)	18/1,595 (1.1%)	81/869 (9.3%)	17/864 (2.0%)	166/878 (18.9%)	79/824 (9.6%)
p-value	<0.001		<0.0001		<0.001	
Symptomatic VTE n (%)	11/2,206 (0.5%)	6/2,193 (0.3%)	3/1,212 (0.2%)	15/1,207 (1.2%)	24/1,217 (2.0%)	8/1,201 (0.7%)
p-value	0.22		0.004		0.005	
Incidence of major bleeding n (%)	2 (0.1%)	6 (0.3%)	1 (<0.1%)	1 (<0.1%)	6 (0.5%)	7 (0.6%)
p-value	0.18		n/a		0.77	

Table 2. Comparison of phase III RECORD trials\*

Total venous thromboembolism (VTE): composite of any deep vein thrombosis, non-fatal pulmonary embolism and all-cause mortality; n/a, not applicable

\* RECORD4 has been completed and is currently being written up for publication



AUTHOR

**Ass. Prof. Andrejs Erglis**  
Associate Professor  
University of Latvia

Chief  
Latvian Centre of Cardiology  
Pauls Stradins Clinical  
University Hospital  
Riga, Latvia

a.a.erglis@stradini.lv

# MANAGEMENT CHALLENGES OF CARDIOLOGISTS IN LATVIA

Taking Steps to Modernise Facilities

In the twenty years since the demise of the Soviet Union, Latvia has transformed itself, gaining its independence not only politically but also in medicine. While formerly, research, innovations and financial investments were concentrated in Moscow and less in the Baltic States, in present times Latvia is a member of the European Union, is independent, and its citizens can make their own decisions and control their own future.

The main challenges for us during the last 20 years have been to reduce the prevalence and incidence of cardiovascular disease and to decrease cardiovascular mortality. The burden of cardiovascular mortality and morbidity is very high in Latvia. According to epidemiologic data, cardiovascular disease emerges as the leading cause of mortality in Latvia (54.6% from total deaths in 2007) (Ministry of Health of the Republic of Latvia 2007).

### Modernising Cardiology Services

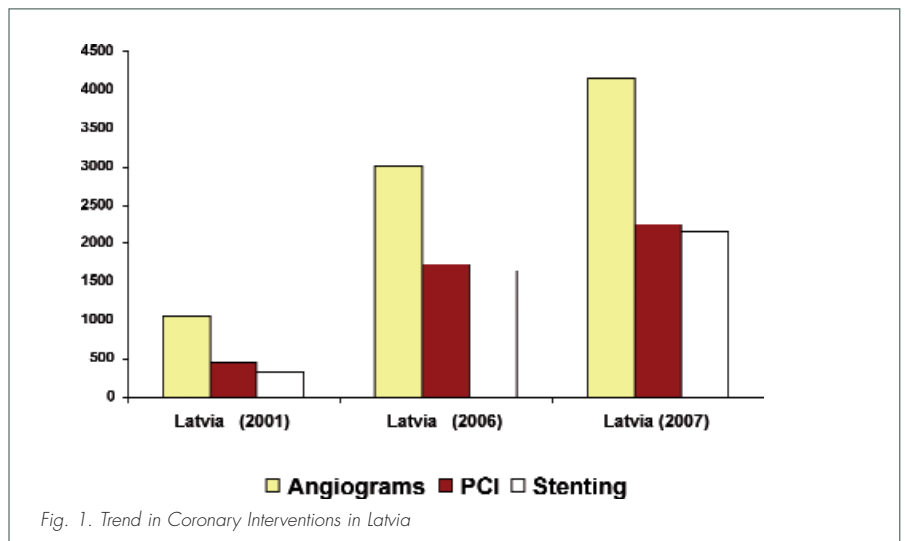
The first step was the introduction of modern diagnostic and management methods, for example, interventional cardiology. Due to insufficient funding in healthcare during the nineties, modern facilities and services were only accessible in the Latvian Centre of Cardiology at Pauls Stradins Clinical University Hospital. Expanding modern medical tools across the country and improving the availability of services were a key factor. Then, in order to evaluate healthcare quality and accessibility the national registry of acute coronary syndrome was introduced in 2001.

### Interventional Cardiology

The most significant advance in cardiology, was during the beginning of the interventional cardiology era in 1990, when myself and Andis Dombrovskis carried out our first angioplasty in Latvia. For the first 15 years the Latvian Centre of Cardiology was the country's only existing interventional centre. Nowadays, it is one of the

largest interventional cardiology centres in Europe, where the newest methods are used and research carried out. Since 2004, regional centres of interventional cardiology have been launched, with three interventional cardiology centres in capital city Riga and two in regional hospitals.

The number of percutaneous coronary



interventions (PCI) per million inhabitants in Latvia continues to increase. In 2007, we had 1,736 percutaneous coronary interventions (PCI) which corresponds to a four-fold increase since 2001 (see fig. 1). The mean number of PCIs per million in Europe in 2005 was 1,601 (Praz et al. 2008). Active usage of intravascular diagnostic devices (intravascular ultrasound, OCT, virtual histology) and modern PCI modalities (LM interventions with cutting balloon pretreatment) have been investigated at the Latvian Centre of Cardiology and introduced into practice (Erglis et al. 2007).

Since 2001, the major non-coronary procedures were introduced at the centre, including alcohol ablation for septal hypertrophy, percutaneous closure of atrial septal defect, patent foramen ovale or ductus arteriosus and percutaneous treatment of aortic coarctation. Recently, we have started to perform percutaneous valvuloplasties and stem cell intracoronary delivery is also now on our list of offered treatments.

### The National Registry of Acute Coronary Syndromes (ACS)

The National Registry of Acute Coronary Syndromes (ACS) was developed to pinpoint if knowledge coming from clinical trials is being properly applied in different hospitals in our country. The aim of this registry was to identify changes in therapeutic approaches and outcomes of ACS patients in Latvia. The study sample consisted of 7,232 patients with ACS in year 2001 and 9,881, 8,261 and 7,777 patients with ACS admitted across all the country in years 2005, 2006 and 2007 respectively.

Randomised trials comparing thrombolysis and PCI show that primary PCI results in lower in-hospital mortality, rate of the reinfarction and stroke (Grines et al. 1993). However, its availability is limited and a large proportion of patients are reperfused with thrombolysis (Morrow et

al. 2005). Although we have at least one interventional centre within a coverage radius of 100km in Latvia, a 24-hour service is available only at our centre. Therefore most other Latvian hospitals are still using thrombolysis. Since 2001, the

implemented in practice. It has resulted not only in changes of management but also in improvement of clinical outcomes, for example, in-hospital mortality (see fig. 3). One of the main areas where more development is required is in the educa-

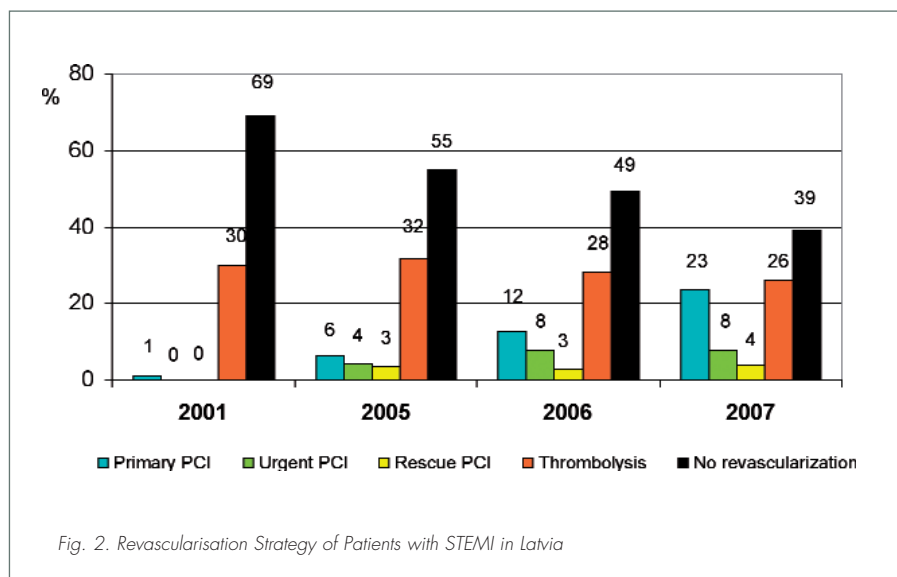


Fig. 2. Revascularisation Strategy of Patients with STEMI in Latvia

use of fibrinolytic therapy has slightly decreased, and the incidence of primary PCI has increased (see fig. 2).

Based on ACS registry data, in 2001, the first Latvian National Guidelines of Acute Coronary Care were developed by the Latvian Society of Cardiology and were

tion of doctors – especially general practitioners and cardiologists. All Latvian interventional cardiologists are trained at excellent interventional centres in different countries like the United States, Australia, France, Netherlands, Germany, and Italy. It is essential to admit that we have trained not just interventional cardiologists but

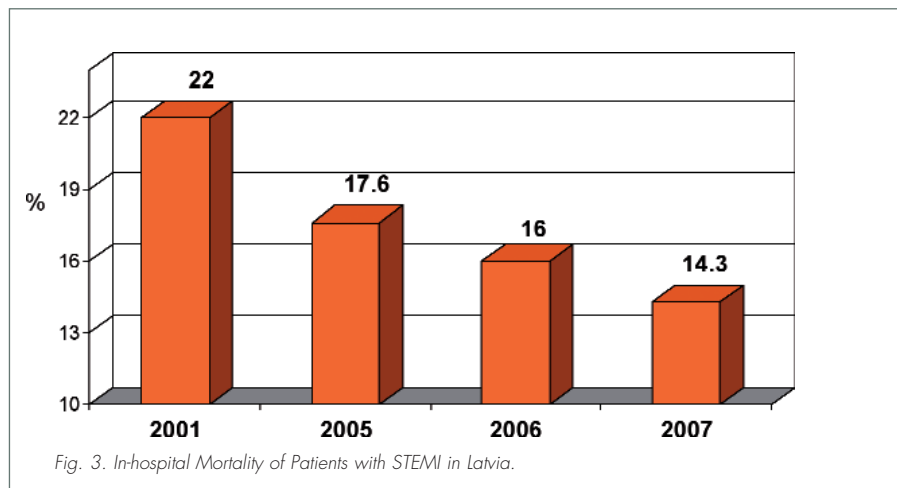


Fig. 3. In-hospital Mortality of Patients with STEMI in Latvia.

# Detection of Abdominal Aortic Calcification with IVA

Kevin E. Wilson, PhD

## The Scope of the Problem

Worldwide, cardiovascular disease (CVD) is the largest single cause of death among women, accounting for one third of all deaths. Atherosclerosis is the common pathological process underlying myocardial infarction, stroke and other occlusive vascular diseases. Atherosclerosis has a long latent period between early phases of the disease and the manifestation of clinical symptoms. Thus there is an opportunity for primary prevention if patients can be identified before the first clinical event. Unfortunately, for many asymptomatic individuals, the first manifestation of underlying disease is often an unexpected acute myocardial infarction or sudden death.

Additionally, there is evidence that in women, coronary heart disease often presents atypically, making clinical recognition difficult. Two thirds of women who died suddenly of coronary heart disease had no prior symptoms.

Traditionally, cardiovascular disease risk stratification has been conducted using risk factors such as cigarette use, diabetes mellitus, systolic blood pressure, dyslipidemia, etc. However, 60% of cardiovascular disease events occur in the population that is at low to intermediate risk by these traditional risk factors. There is thus an urgent need for identifying patients at high risk of cardiovascular events using risk factors that are

both strong and independent of the traditional cardiovascular risk factors, and this need is particularly acute in women.

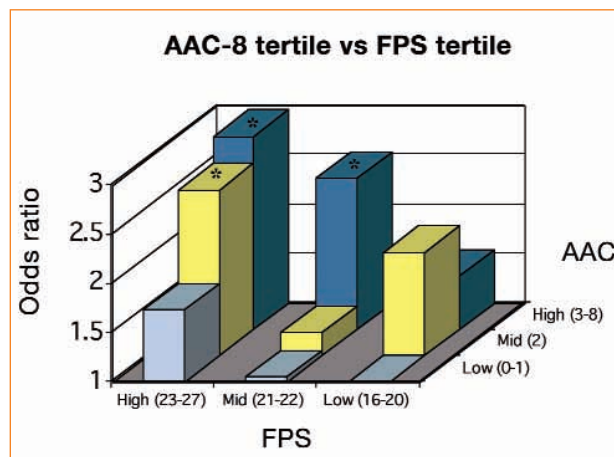
Abdominal aortic calcification (AAC), an indication of atherosclerosis, is significantly associated with both cardiovascular heart disease and stroke even after adjustment for the traditional risk factors of age, cigarette use, diabetes mellitus, systolic blood pressure, left ventricular hypertrophy, body mass index, cholesterol, and HDL cholesterol.

Another major health problem in women is osteoporosis. One in three women over the age of 50 will experience an osteoporotic fracture in their lifetime, very similar to the incidence of cardiovascular disease. The total direct medical costs of osteoporotic fractures in Europe was 31€ billion in the year 2000. A women 65 years of age with a vertebral fracture has a one in four chance of another fracture within the next five years, but that can be reduced to one in eight if she receives treatment.

## Detection of Abdominal Aortic Calcification with IVA

Instant Vertebral Assessment (IVA) has become a valuable and increasingly utilized tool to assess patients at risk of osteoporosis for the presence of vertebral fractures. Prevalent vertebral fractures predict future fractures independently of other risk factors such as age and BMD. This fact, along with IVA's low radiation dose and 10s exam time has contributed to its increasing utilization.

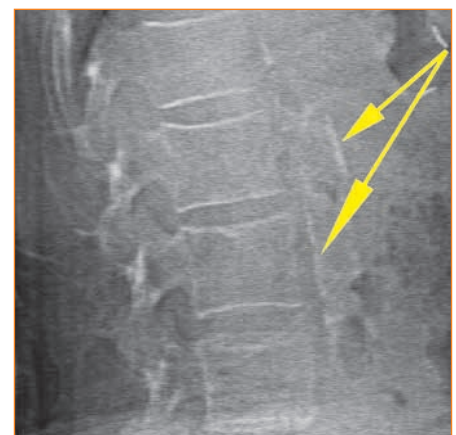
Because of the expected prevalence of vertebral fractures, IVA exams are most typically performed in women age 65 or older. This



Incident MI or stroke in elderly women associated with abdominal aortic calcification detected with IVA within three levels of the Framingham point score. Asterisk indicates statistically different from unity. Adapted from Schousboe et. al. JBM 2008 Mar;23(3): 409-16.

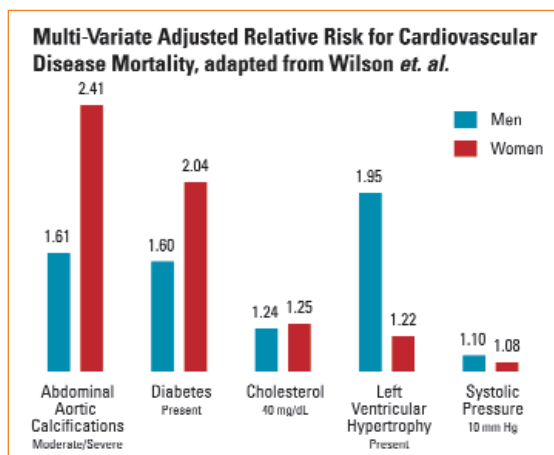
Because of the expected prevalence of vertebral fractures, IVA exams are most typically performed in women age 65 or older. This

Because of the expected prevalence of vertebral fractures, IVA exams are most typically performed in women age 65 or older. This



An example of an AAC-8 score of four. Two each on the anterior and posterior walls of the aorta.





Multi-variate adjusted relative risks of various CVD risk factors. Adapted from Wilson, P.W. (in italics et. al.) *Circulation*, 2001. 103(11): p.1529-34.



An example AAC-8 score of seven, four on the posterior aortic wall and three on the anterior aortic wall.

AAC and carotids IMT was seen for the prediction of incident myocardial infarction. One way to understand the strength of the AAC risk factor is to compare it to the risk from total cholesterol. Each 40 mg/dL increase in total cholesterol above baseline (243mg/dL in the Framingham study) has a RR of 1.25 in women. The RR associated with moderate/severe AAC is 2.4, or equivalent to the relative

is an important period in which to more accurately assess cardiovascular risk in women, since the average age of first myocardial infarction in women is 70.4 years. During an IVA scan, sufficient soft tissue anterior to the lumbar spine can be included to allow for the detection of calcified plaques in the abdominal aorta. There is good agreement between IVA and lateral radiographs for the detection of AAC, similar to the agreement between the two modalities for vertebral fracture detection. Thus, the same diagnostic test can be used to measure strong risk factors for two highly prevalent public health problems, osteoporosis and cardiovascular disease. There are several methods available for the quantification of AAC. One quick and simple method was developed by Schousboe, Wilson, and Kiel and is called AAC 8. The AAC 8 scale estimates the total length of calcification of the anterior and posterior aortic walls in front of vertebrae L1 to L4. Abdominal aortic calcification is typically seen as a linear stippling at the anterior or posterior wall of the aorta or alternatively there is a “ground glass” appearance seen instead of a linear calcification. To be considered a calcification, this “ground glass” appearance needs a definite linear edge corresponding to the aortic wall. Both linear calcifications and “ground glass” are considered part of the aggregate length of the calcification. The

anterior and posterior aortic walls are assigned a score between 0-4 as shown in the table (below). The sum of the two scores for the anterior and posterior walls gives the AAC 8 score. An AAC 8 score greater than two is considered moderate to severe AAC on this scale.

### The Clinical Significance of Abdominal Aortic Calcification

The multivariate adjusted relative risk for cardiovascular disease mortality for those with AAC in the upper one third of the population was 2.4 for woman and 2.2 for men. On the AAC 8 scale, this is roughly equivalent to a score greater than two. The fact that the AAC risk is independent of other typically assessed cardiovascular risk factors gives this measure particular strength. In fact, for the prediction of stroke, “Carotids IMT and aortic calcifications predict the risk of stroke independently of each other.” Similar independence of the predictive power of

risk a women would have with a total cholesterol of 400 mg/dL.

Coronary calcium scoring with electron beam CT (EBCT) or multislice CT has gained some acceptance for identifying those at high risk for heart disease. Strong and graded associations have been shown between coronary calcium score and AAC. In women, severe AAC was associated with a 20 fold increase in coronary calcium score as assessed by EBCT, and there was an 11 fold increase for men. In summary, IVA’s new indication for the detection of abdominal aortic calcifications may have as much clinical significance as its previous indication for the detection of vertebral fractures. Most patients at high risk for osteoporotic fracture are commonly also at high risk for cardiovascular disease. A single IVA exam can assist in stratifying patients into high and low risk groups for two highly prevalent and significant health care problems.

Description	Score
No calcification seen	0
Aggregate length of calcification is ≤ to the height of one vertebra	1
Aggregate length of calcification is > one but ≤ two vertebra	2
Aggregate length of calcification is > two but ≤ three vertebra	3
Aggregate length of calcification is > three vertebra	4

# AUTHOR GUIDELINES

## Content

Cardiology Management welcomes submissions from qualified, experienced professionals active in the imaging industry, related technology companies and medical healthcare professionals with an interest in imaging-related topics and themes. We are particularly interested in articles focusing on management or practice issues and therefore accept scientific papers with a clear connection to these areas. Articles must be written by independent authorities, and any sponsors for research named. Our editorial policy means that articles must present an unbiased view, and avoid 'promotional' or biased content from manufacturers.

## Submission guidelines

Authors are responsible for all statements made in their work, including changes made by the editor, authorised by the submitting author. The text should be provided as a word document via e-mail to [editorial@cardiologymanagement.eu](mailto:editorial@cardiologymanagement.eu). Please provide a contact e-mail address for correspondence. Following review, a revised version, which includes editor's comments, is returned to the author for authorisation. Articles may be a maximum 700 words per published page, but may include up to 1,500 words in total.

## Structure

Article texts must contain:

- names of authors with abbreviations for the highest academic degree;
- affiliation: department and institution, city and country;
- main authors are requested to supply a portrait photo (see specifications below);
- one contact name for correspondence and an e-mail address which may be published with the article;
- acknowledgements of any connections with a company or financial sponsor;
- authors are encouraged to include checklists, tables and/or guidelines, which summarise findings or recommendations;
- references or sources, if appropriate, as specified below.

## Images

Main authors are invited to supply a portrait photo for publication with their article, as well as other images and visuals. This and any other relevant images for publication with an article should be sent by e-mail as separate files (only high

resolution images with 300dpi) and their order of placement in the article must be clearly indicated. Only the electronic formats `_.tif_` or `_.jpeg_` can be used for images, i.e. not Microsoft Word or PowerPoint. Images must be no smaller than 9cm • 9cm at 100% scale. Only images meeting these specifications can be published. If an image has been published before, permission to reproduce the material must be obtained by the author from the copyright holder and the original source acknowledged in the text, e.g. © 2004 Dervla Gleeson.

## Format for references

Please use the Harvard reference system. Citations within the text for a single author reference should include the author surname and year of publication; for a citation with two authors include both author surnames and year of publication; for more than two authors, include the first author surname followed by "et al." and the year of publication. Multiple citations should be separated by a semicolon, and listed in alphabetical order. Example of within text citation: (Marolt 2008; Marolt and Gleeson 2002; Miller et al. 2003).

The format for listing references in submitted articles should follow the Harvard reference system. Example of standard journal reference: Sydow Campbell, K. (1999) "Collecting information; qualitative research methods for solving workplace problems", Technical communication, 46 (4) 532-544. Readers will be provided with an e-mail contact for references, which will be kept on file and supplied on request. Authors are responsible for the accuracy of the references they cite.

## Acceptance

It is at the discretion of our editorial board to accept or refuse submissions. We will respond to submissions within four weeks of receipt. We reserve the right to revise the article or request the author to edit the contents, and to publish all texts in any EMC Consulting Group journal or related website, and to list them in online literature databases.

For further details or to request a copy of the 2008 editorial planner, with topics and focus areas included, please email [edi.torial@cardiologymanagement.eu](mailto:edi.torial@cardiologymanagement.eu)

Thank you,  
The Cardiology Management Editorial Team



## INTERVIEWEE

**Prof. Roberto Ferrari**  
President  
European Society of  
Cardiology (ESC)  
European Heart House  
Sophia Antipolis, France

Firstly, congratulations on your new appointment as ESC President 2008 – 2010. Do you feel you have now reached the greatest heights in your professional life?

Yes, I consider the Presidency of the ESC a great honour.

Which of your previous roles within the ESC are close to your heart?

- Co-chairman of the Working Group on Pathophysiology of the Cardiac Myocyte from 1992 – 94;
- Chairman of the Working Group on Cellular Biology of the Heart from 1994 – 96;
- One of the founders of the Working Group on Heart Failure;
- Board Member since 2002;
- Chairman of the Education Committee from 2002 – 2004;
- Vice-President and Chairman of the Associations, Working Groups and Councils from 2004 – 2006, and
- Translational science.

Please tell us about your intended 'grand tour' of other ESC societies.

I believe that it is about time the ESC became closer to the national societies and

## INTERVIEW WITH PROF. ROBERTO FERRARI, PRESIDENT OF THE EUROPEAN SOCIETY OF CARDIOLOGY

particularly to those in transition. By visiting them, spending time with the leadership, by attending their meetings, and by establishing human relationships, I believe I can make some progress to this end.

In what new directions do you intend to lead the ESC during your tenure there? What will be your biggest challenge?

I would like to learn more about how our society functions, and I need to have clear ideas on the long-term strategy. During my term, there will be major changes, and the biggest challenge will be to consolidate the achievements obtained so far, and to ensure compliance with long-term strategy.

Concerning your sabbatical from your clinical duties as Professor of Cardiology at the University of Ferrara in Italy – do you feel your tenure as President of ESC will enhance your role there, once you return?

Cardiology in Ferrara is a big family. I believe I am appreciated as Roberto Ferrari, but of course the fact that I have been elected President of the ESC is important for me and for the entire family of cardiology.

How will the ESC reach out to include other developing countries?

We aim to be more inclusive by communicating more, by attending as many national congresses as possible, by inter-

acting with the leadership of each national society, and by being available to talk to the relevant politicians if necessary.

The ESC is continually expanding. Not only this, but attempting to harmonise standards within a fragmented European landscape provides a unique challenge. How will you ensure the ESC does not become fragmented?

Many organisations in Europe have similar missions to ours, and we should liaise and collaborate with all of them. For this purpose we have set up five Councils, which have the specific mission of liaising with different European scientific organisations. Equally we have set up the European Relations Committee, which has the mission of liaising with different healthcare organisations.

I have already included the Chairman of the associations as ex officio members of the Board, and I would like to have representatives of the national societies and working groups on the Board as well. This indeed would improve communication and reduce fragmentation.

Will the ESC continue to expand its work on guidelines and implementation?

This will be one of our major tasks, and indeed we will continue to disseminate knowledge and implement the guidelines. ■



AUTHOR

**Prof. Frank Misselwitz**  
Bayer HealthCare AG  
Wuppertal, Germany

frank.misselwitz@bayer-healthcare.com

## RIVAROXABAN: LOOKING TO THE FUTURE

Rivaroxaban (Xarelto®) is a novel, oral, direct Factor Xa (FXa) inhibitor that has recently received marketing authorisation in the European Union and Canada for the prevention of venous thromboembolism (VTE) after total hip or total knee replacement surgery. The ongoing rivaroxaban clinical development programme will enrol approximately 50,000 patients and will evaluate rivaroxaban in a wide range of acute and chronic thromboembolic indications. These indications include VTE treatment, stroke prevention in patients with atrial fibrillation, VTE prevention in hospitalised, medically ill patients and secondary prevention of ischaemic events in acute coronary syndrome (ACS).

### Characteristics and Mechanism of Action

Rivaroxaban is administered orally and has high bioavailability (Kubitza et al. 2005). It is one of a new class of agents designed to directly inhibit FXa, one of the enzymes of the coagulation cascade. FXa is a rational target for the development of anticoagulants because it is involved in both the initiation and propagation of the coagulation process and, to-

gether with Factor Va, is responsible for the conversion of prothrombin to thrombin.

FXa is also responsible for a range of other prothrombotic effects suggesting that direct inhibition of FXa restricts thrombin production and thrombus development in multiple ways. Rivaroxaban acts by binding directly to the active site of FXa and can inhibit both free and fibrin-bound FXa as well as FXa in the prothrombinase complex. Because of its direct mechanism of action, rivaroxaban does not require cofactors such as antithrombin to exert its regulatory effect on coagulation. Rivaroxaban is highly selective and therefore has limited effects outside the coagulation cascade (Perzborn et al. 2005).

### Advantages Over Traditional Anticoagulants

Traditional anticoagulants, including the vitamin K antagonists (VKAs), unfractionated heparin (UFH) and low molecular weight heparins (LMWHs) have a number of limitations. In comparison with rivaroxaban, which specifically targets one factor in the coagulation cascade, the more traditional agents have multiple

targets, resulting in less predictable pharmacokinetics and pharmacodynamics. The VKAs, such as warfarin, are administered orally. However, they have a narrow therapeutic window and numerous food and drug interactions (Ansell et al. 2008).

To maintain patients on warfarin therapy within the target therapeutic range (international normalised ratio [INR] 2 – 3), regular monitoring and dose adjustments are necessary. Patients below the target INR are at increased risk of thrombosis and those above this range are at increased risk of serious bleeding events. In addition, warfarin has a slow onset of action (approximately 2 to 5 days) and offset of action. In high-risk patients, initial bridging therapy may be necessary to reduce the risk of thrombosis. Conversely, because of the slow offset of action of warfarin, its anticoagulant effects cannot be rapidly reversed by cessation of therapy, although vitamin K can be administered as an antidote. UFH is administered as a continuous intravenous infusion, and LMWHs (e.g. enoxaparin) require once-daily or twice-daily parenteral administration, making them less convenient for use in an outpatient set-

ting. Patients receiving UFH must also be monitored regularly as they are at increased risk of heparin-induced thrombocytopenia (Hirsh et al. 2008).

The benefits of rivaroxaban include convenient oral, fixed dosing, with no requirement for routine coagulation monitoring. Rivaroxaban has predictable pharmacology, limited interaction with food and a low propensity for drug–drug interactions (Mueck et al. 2008). These benefits could potentially lead to improvements in patient compliance, reduced costs and support easier transition between hospital and outpatient care.

### The RECORD Programme

The RECORD (Regulation of Coagulation in ORthopaedic surgery to prevent Deep vein thrombosis and pulmonary embolism) clinical trial programme, completed earlier this year, was the largest

son of extended-duration (five weeks) rivaroxaban with short-duration (two weeks) enoxaparin (RECORD2), the extended-duration regimen was significantly superior in terms of efficacy.

Rivaroxaban demonstrated significantly superior efficacy compared with enoxaparin in head-to-head comparisons (RECORD1, 3 and 4). In RECORD4, rivaroxaban was the first oral anticoagulant to demonstrate superior efficacy over the North American-approved 30 mg twice-daily subcutaneous regimen of enoxaparin. In all four trials, rivaroxaban and enoxaparin demonstrated similar safety profiles with similar rates of major bleeding.

### The Future

Rivaroxaban is also being evaluated for VTE treatment in a phase III study of patients with acute symptomatic deep vein thrombosis (EINSTEIN DVT

patients is ongoing (MAGELLAN), and rivaroxaban is being compared with warfarin for stroke prevention in patients with atrial fibrillation (ROCKET AF).

Finally, rivaroxaban in combination with acetylsalicylic acid (ASA) alone or with ASA and a thienopyridine is being investigated in a phase II study of subjects with ACS (ATLAS ACS TIMI 46 trial).

### Rivaroxaban in Acute Coronary Syndromes

A phase II study (ESTEEM) showing that ASA in combination with ximelagatran was more effective than ASA alone after an ACS, highlighted the potential benefit of using anticoagulants in this indication (Wallentin et al. 2003). Proof of concept for FXa inhibition in ACS was demonstrated by the indirect FXa inhibitor fondaparinux in the OASIS-5 and OASIS-6 trials (Mehta et al. 2007; Yusuf et al. 2006).

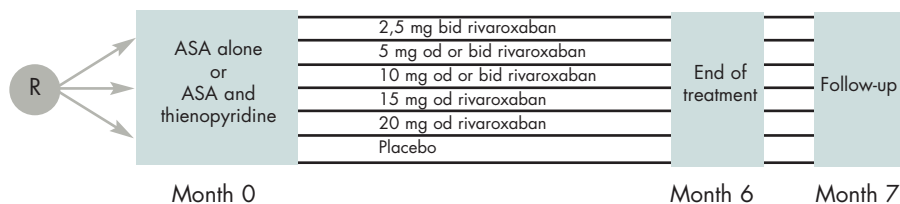


Figure 1. ATLAS ACS TIMI 46 study design

ASA, acetylsalicylic acid; bid, twice daily; od, once daily

programme to date to investigate the prevention of VTE in patients undergoing total hip or total knee replacement surgery.

More than 12,500 patients were enrolled in four pivotal phase III clinical trials that compared oral rivaroxaban regimens with subcutaneous enoxaparin (40 mg once-daily) (Eriksson et al. 2008; Kakkar et al. 2008; Lassen et al. 2008). In a compari-

evaluation) or acute symptomatic pulmonary embolism (EINSTEIN PE evaluation), and for long-term prevention of recurrent symptomatic VTE in patients with symptomatic deep vein thrombosis or pulmonary embolism (EINSTEIN extension study).

A phase III study of rivaroxaban for VTE prophylaxis in medically ill

### Disclaimer

"Xarelto® (rivaroxaban) is licensed in the EU and in Canada for the prevention of venous thromboembolism following elective total hip or knee replacement. The data contained within this article do not support or recommend the use of Xarelto in any other indication or countries in which it is not licensed."

# Free Subscription Form



Title & First Name: \_\_\_\_\_

Surname: \_\_\_\_\_

Job Title: \_\_\_\_\_

Institution: \_\_\_\_\_

Address: \_\_\_\_\_

Postcode & City: \_\_\_\_\_

Country: \_\_\_\_\_

Telephone: \_\_\_\_\_

Email: \_\_\_\_\_

## How to Subscribe?

- Send an email with name and address to office@cardiologymanagement.eu;
- Complete this form and post it to 28, rue de la Loi - B-1040 Brussels - Belgium;
- Complete this form and fax it to +32 2 286 8508.

### Medical Doctors (respond below)

1. What is your occupation? (check only one)
- Chief Cardiologist
- Other Physician (please specify)
- 1a. What is your Cardiology sub-specialty? (check only one)
- General Cardiology
- Interventional Cardiology
- Cardiac Radiology (Cardiac MRI, Echography, Cardiac CT)
- Cardiac Surgery/ Cardiovascular Surgery
- Paediatric Cardiology
- Other (please specify)
- 1b. I am Chief of my Department
- Yes
- No

### Non-physician professionals (respond below)

- 1c. What is your occupation? (check only one)
- Administrator/Manager:
- Cardiology Administrator
- Cardiology Business Manager
- Cardiology PACS Administrator

### Executive

- Chief Information Officer / IT Manager
- Chairman / Managing Director
- Director
- Chief Financial Officer / other executive titles

### Other

- Medical Physicist
- Academic
- Chief Technologist
- Manufacturer
- Business Consultant
- Distributor / Dealer

### All respondents reply to the questions below

2. In what type of facility do you work? (check only one)
- Private clinic
- Hospital (check number of beds)
- More than 500 beds
- 400-499 beds
- 300-399 beds
3. How many beds is your ward equipped with?
- More than 30 beds
- 15 - 30 beds
- Less than 15 beds
4. With what technologies or disciplines do you work? (check all that apply)
- Echography
- Interventional Cardiology
- Angiography
- Cardiac CT
- Cardiac MRI
- Cardiology PACS
5. What is your role in purchasing
- Final say
- Influence
- No role

**FAX BACK TO +32 2 286 8508**

# ESC Congress 2009

29 August -  
2 September

*Barcelona*



EUROPEAN  
SOCIETY OF  
CARDIOLOGY®

[www.escardio.org](http://www.escardio.org)



AUTHOR

**Prof. S. Sujanthy Rajaram**  
Assistant Professor of Medicine

**Prof. Carolyn Bekes**  
Professor of Medicine

Cooper University Hospital  
New Jersey, US

rajaram-sri-sujanthy@cooperhealth.edu

## OVERVIEW OF HEALTHCARE IN AMERICA

Disparity in Access to Medical Coverage  
Continues to Provoke

The United States is the only wealthy industrialised nation without a universal healthcare system, according to the Institute of Medicine of the National Academy of Sciences. It has a mixed system of public and private insurance. Most working-age Americans have private health insurance through their employers. Private health insurance covers about 57% of the population, while only 27% is insured through government-funded means (US Census Bureau, 2007).

Over 15.5% of Americans do not have health insurance and about half of bankruptcies in the US involve a medical reason or large medical debt. Private and government programmes for healthcare exist and are explained below (US Census Bureau 2007).

### Private Programmes

1. Health Maintenance Organisations (HMOs): An HMO is a prepaid “managed” health plan delivering comprehensive care to members through designated providers, having a fixed periodic payment for health services.
2. Preferred Provider Organisations (PPO): A PPO has arrangements with doctors, hospitals and other providers who have agreed to accept the plan’s allowable charges for covered medical services that are similar to a fee-for-service plan. This gives patients a choice of using doctors and hospitals in a network with a co-payment and

outside network with an annual deductible and a percent of the bill.\*\*Approximately 50% of the US population is enrolled in one of these two programmes, with about 29.3% enrolled in an HMO and 19.8% in a PPO (MCO, 2008).

### Government Programmes

1. Medicare: A federal programme provides health insurance to all Americans over 65 years of age, persons with disabilities and end-stage renal disease.
2. Medicaid: This health insurance programme provides for certain low-income families with children; aged, blind, or disabled people on supplemental security income, certain low-income pregnant women and children, and people who have very high medical bills. Medicaid is funded and administered through a state-federal partnership. Although there are broad federal requirements for Medicaid,

states have a wide degree of flexibility to design their programme. However all states must cover basic services: inpatient and outpatient hospital services, skilled nursing and home health services, family planning, and periodic health check ups. Medicaid reaches about 40% of Americans at the 100% poverty level (defined as an annual income of 9,570 dollars for a family size of one person; Dept of Health and Human Services 2005; US Census Bureau 2006).

3. State Children’s Health Insurance Programme (SCHIP): This provides health benefits coverage to children living in families whose income exceeds the eligibility limits for Medicaid with incomes at or below 200% of the federal poverty level (annual income of 32,180 dollars for a family size of 3).
4. There is also a military plan for active and retired servicemen and women.



# “Managed care has had a profound impact on the delivery of medical service”

## Healthcare Statistics and Costs

In 2008 the life expectancy in the US is 78 years of age, according to the CIA Factbook. Deaths from heart disease, cancer and stroke continue to drop (National Centre for Health Statistics 2005). Heart diseases are the number one cause of death followed by malignant neoplasm and cerebrovascular diseases (ibid). Infant mortality has dropped to 6.9 deaths per 1,000 live births.

Healthcare spending reached 16% of GDP in 2007, making the total estimated National Health expenditure 2.3 trillion dollars (NCHC, 2007). National healthcare expenditures are projected to reach 3.6 trillion dollars (18.7% of GDP) in 2014, growing at an average annual rate of 7.1% per year from 2003 to 2014 (Centres for Medicare and Medicaid Services 2004 & 2005). Intensive care units spend 10 - 30% of a hospital budget which accounts for to 0.5 - 1% of the GDP (Polderman and Metnitz 2005).

The US has the highest per capita health expenditure of any nation (Anderson et al. 2003). It is estimated that 7,500 dollars were spent in 2007, per US resident (Kaiser Family Foundation, 2007). Prescription drugs have been the fastest growing expenditure, increasing at a rate

of 11% over the last three years. The US had fewer physicians and hospital admissions per 1,000 population, physician visits per capita, acute care beds and acute care days per capita than the median of industrialised countries (Anderson et al. 2003).

## US Healthcare System: An Analysis

A rapidly emerging trend in every American metropolitan area is the formation of health networks made up of hospitals, physicians and insurance underwriters. Managed care, an organised way to manage the cost, use and quality of the healthcare system has had a profound impact on the delivery of medical services, transforming traditional insurance arrangements (Oberlander 2002).

Most studies have found little difference in quality of care between traditional insurers and managed care plans, though there is evidence of worse outcomes for chronically ill seniors in HMOs (Miller and Luft 1997). The functional status of the elderly has improved recently and there is a decreased death rate. Recent advances are cost effective at generally accepted values of an added year of life (Cutler and McClellan 2001).

## Rising Costs Hit Employers

While rising costs may not create major

problems for the economy as a whole, they negatively affect employers, employees, government and patients. The aging population is not an adequate explanation for the increased cost since it is too gradual a process to rank as a major cost driver in healthcare (Reinhardt 2003). The lack of well-developed competitive markets in healthcare may be partially responsible for the higher expenditure.

The US has the highest cost per unit of care, physician fees, payment per hospital day and pharmaceutical prices. Even though physician visits and hospital days per capita have been lower in the US than many other developed nations, use of expensive technologies, market power of hospitals and physicians, who are able to garner high prices for services, more rapid diffusion of innovative technologies, and a higher cost for administering the healthcare system has driven the overall healthcare costs to be high (Bodenheimer 2005).

One proposed driver of healthcare spending growth is the medical malpractice system, which encourages physicians to practice “defensive medicine” by ordering unnecessary diagnostic tests or treatments to avoid malpractice litigation (Anderson 1999). Defensive medicine may account for 5 - 9% of health expenditure (Hessler and McClellan 1996).

Approximately 63% of growth in health-care spending is the result of an increased prevalence of obesity, stress, ozone, changing treatment threshold for hypertension, diabetes, hyperlipidaemia and osteoporosis and new innovations like statins, antidepressants, and other medications (Thorpe et al. 2005). Treatment of low-birth weight babies and heart attacks has also accounted for 37% of growth in healthcare spending (ibid). ■



AUTHOR

**Dr. Michael Cobble**  
 Director  
 Canyons Medical Center  
 Utah, US

mcobble@canyonsmedical.com

## MOTIVATING PATIENTS TO GET INVOLVED IN PREVENTION

EUROASPIRE III Trial Mirrors US Struggle to Empower Patients

This article addresses early identification and prevention of cardiovascular disease, to highlight the challenges in motivating patients to participate in their health and well being and focus on motivating insurance companies and national healthcare to empower, enable and encourage better health.

National policies have been ineffective at promoting lifestyle changes that could extend both the quality and quantity of one's life. My father suffered an unstable angina event in his early 50's. He is healthier today than 20 years ago through optimal medical management, surgery and lifestyle management – all complementary to each other. This, however could not have been accomplished without his active participation or the medical resources at our disposal.

### ABC's of CV Risk Reduction

In his case, we implemented the ABC's of cardiovascular (CV) risk reduction (RR) based on the continuing body of evidence-based medicine (EBM). These are:

- A.** ASA (acetylsalicylic acid – aspirin), ACEI (angiotensin converting enzyme inhibitor) or ARB (angiotensin receptor blocker) if ACEI intolerant or both if indicated, ADPI (adp inhibitor) if indicated, AldoI (aldosterone inhibitor) if indicated;
- B.** BB (beta blocker - preferably not atenolol or bucindolol);
- C.** Cholesterol modification therapy based on national and international guidelines;

**D.** Dietary changes – DASH diet, Mediterranean diet, etc;

**E.** Exercise changes;

**F.** Fibrate therapy if appropriate based on guidelines;

**G.** Glucose therapy if appropriate based on guidelines, and

**H.** Healthy lifestyle changes such as annual physicals, cancer screening, tobacco cessation, salt reduction, alcohol modification, safety counseling (seat belts, helmets, etc.), multivitamin therapy, medication compliance, clinical visit compliance, etc.

Despite national and international guidelines targeting blood pressure goals, blood sugar goals, tobacco cessation goals, weight loss, exercise, nutrition goals and lipoprotein goals, still less than 50% of our populations reach such goals. Managed care to date after three decades has not been proven effective in assisting with goal achievement.

Insurance companies often penalise the patient, the clinician and the healthcare system. This discourages patient compliance, clinician medical delivery and when

added to limited resources of access and affordability, harms our ability to limit major adverse coronary events (MACE).

### EUROASPIRE III Trial Reinforces Guidelines Failings

EUROASPIRE III presented at the recent European Society of Cardiology (ESC) Congress reinforced how, for patients with risk factors for ASCVD, lifestyle changes and efforts to meet prevention guidelines are abysmal. For those patients with risk for ASCVD only 1 in 10 smokers have quit, nearly 50% are overweight, over 75% have blood pressure and lipoprotein values exceeding goals, less than 30% of people with DM2 are meeting fasting glucose goals and barely over 50% are reaching A1c goals.

EUROASPIRE III is in line with struggles faced in the United States showing less than 40% of our high risk patients meeting guidelines and less than 20% of very high risk patients meeting guidelines. The real surprises were that over 80% of patients wanted to know their risk score for heart disease and more than

80% had not been provided professional risk factor management programmes or lifestyle counseling.

The other issues for risk reduction include clinician lack of inertia and patient compliance. Two major factors for noncompliance by patients were:

1. 'My clinician did not tell me how important the treatment was.'
2. 'My clinician did not tell me how long I would need to follow this treatment.'

Three major factors for optimal glucose management in DM2 were:

- Explaining to the patient what the A1c value represents: '3-month glucose average'.
- Explaining to the patient what their current A1c value was.
- Explaining to the patient what their A1c target goal was.

We must discuss goals in terms the patient will understand: "Each of these medications and changes will make you live better and longer. They along with lifestyle changes will add quality and quantity to your life". Also, we can show a before and after risk prediction which is very powerful.

### Screening for ASCVD Risk

The best way to screen for ASCVD risk is risk screening tools such as Framingham risk scoring (FRS) or Reynolds risk scoring (RRS), or SCORE, HEARTSCORE, QRISK, ASSIGN, PROCAM, etc... The more recent general cardiovascular disease risk profile giving a heart age/vascular age (GCVDR or CVRS – cardiovascular risk score) has been most complementary for us in addition to the FRS and national cholesterol education programme (NCEP) risk factors and risk assessment.

For baseline risk we use NCEP, FRS and CVRS to give us a baseline for ten year risk and heart age/vascular age as well

as evaluating if one has low risk, moderate risk, moderate high risk, high risk or very high risk. Sharing numeric and visual values with patients is very motivating for prevention, risk stratification and risk reduction strategies.

This is part of our 'simple' approach to risk assessment and takes less than five minutes to provide a score. The next approach (intermediate) is if a person shows moderate or higher risk based on any of these three simple tools (NCEP, FRS, CVRS) we will perform moderately advanced testing (expanded lipids and glucose testing) to better stratify risk. These can be included based on cost, access and regional availability.

Vascular imaging can include CIMT, EBT CACS, ABI or in symptomatic patients – stress echo, MPI, CTA, CCA. We favor noninvasive tests for asymptomatic patients for obvious reasons and find them to be inexpensive. Each of these imaging studies have shown independent risk stratification and ASCVD identification further motivating the clinician and patient. Biomarker testing depending on patient risk and symptom profiles includes: UMA, LpPLA2, HsCRP, BNP, expanded lipid testing, serum Cr for estimated GFR. Each of these tests also helps direct medical care. Finally the 'advanced' approach after simple screening and intermediate test-

ing would be to develop a plan with each patient using the ABC's of CV RR with EBM.

### Empowering Patients

We must implement evidence-based strategies to reduce risk and monitor patients for compliance and adherence. Reward, encourage and empower patients, develop mutually acceptable strategies that will benefit them over the long run. Prevention both primary and secondary is invaluable. Risk assessments, risk stratification, simple imaging, advanced imaging, simple biomarker testing, empowering the patient to be involved and compliant, frequent reinforcement, and finally some motivation

**“Managed care to date has not been proven effective in assisting with goal achievement.”**

for insurances and national health policy to commit for life > 80-90 years to improve the health and welfare of the community is crucial.

It's time to implement policies that avert the event. If this is not done we won't have the resources to address those events that do occur. Our responses to cardiovascular events are applauded with faster response times, greater awareness and technological advances. To be even more progressive, action must be taken to identify risk and disease earlier and encourage all entities to implement changes we know limit such risk. ■

# PROFILE OF THE AMERICAN HEART ASSOCIATION

Building Healthier Lives

**The American Heart Association mission is building healthier lives, free of cardiovascular diseases and stroke. To accomplish this, its volunteers and organisation are involved in an extremely broad range of activities.**

The activities of the Association systematically attack the problem of cardiovascular disease across the knowledge spectrum in the following ways:

- Discovering knowledge through research;
- Adapting knowledge for different audiences by offering information in different formats, levels of difficulty and languages, and
- Disseminating knowledge through a variety of materials, media, activities and services.

To focus its efforts, the association set a strategic goal in 1999 to reduce coronary heart disease, stroke and risk by 25 percent by the year 2010. Working to achieve this goal has enabled the association to prioritise resources and activities.

To achieve this goal, it funds research, conducts professional and public education programmes, offers community services and is engaged in advocacy efforts with local, state and national elected officials.

## About the American Heart Association

The American Heart Association is divided physically into the National Center

(located in Dallas, Texas) and eight affiliate offices that cover the United States and Puerto Rico. Operations are divided into seven main areas that are listed below.

Millions of volunteers and donors support their efforts every year. The American Heart Association and its division, the American Stroke Association, are working hard to protect the population from heart and stroke, the number 1 and 3 killers.

Since 1924 the association a national voluntary health organisation has shared information and invested resources to create lifesaving advances and make communities safer from heart disease and stroke.

## Research a Priority

Funding medical research at national and state levels is a key association priority. Supporting the work of outstanding researchers helps discover knowledge that benefits all Americans. Ten Nobel Prizes have been awarded to researchers for work funded by the association.

To help achieve the goal of reducing coronary heart disease, stroke and risk by 25 percent by 2010, the association tar-

gets various key groups. A wealth of programmes, products and services are offered to help people learn how to reduce their risk:

- Call-to-action campaigns highlight real people touched by heart disease and stroke to raise awareness and inspire Americans to reduce their risk.
- Online and telephone outreach services provide hope and information 24/7 to people throughout the nation.
- Community education programmes spread lifesaving information while encouraging healthier lifestyles.
- Labels on certified foods help consumers shop smarter and eat healthier to lower their risk of cardiovascular disease.
- Cookbooks help people cook healthier to live longer.

## Targeted Programmes for High-Risk Groups

Heart disease and stroke threaten all Americans, but members of certain racial/ethnic groups are at particularly high risk. The association offers programmes specifically targeted to meet the needs of people in these groups.

Patients are another key group. Association education programmes, products and services help patients learn and make

healthy changes to prevent or manage disease. Caregivers and healthcare professionals rely on association materials for their loved ones and patients.

Through its American Stroke Association division, the association supports stroke programmes to reduce disability and death and promote rehabilitation and recovery. Local programmes help local communities offer the best possible care for stroke patients, their families and their caregivers.

### What is the American Stroke Association?

The American Stroke Association is a division of the American Heart Association that focuses on reducing risk, disability and death from stroke through research, education, fund raising and advocacy. The American Heart Association created the American Stroke Association after many years of increasing emphasis on stroke. It spends more money on stroke research and programmes than any other organisation except the federal government.

### Stroke a Strategic Priority

The American Heart Association views stroke as a strategic priority because of its significant impact on the American public. Stroke is the third leading cause of death in the United States and a major cause of serious, long-term disability.

On average, someone suffers a stroke every 45 seconds. Someone dies of a stroke every three minutes. The American Stroke Association offers a wide array of programmes, products and services, from patient education materials to scientific statements.

### Professional Education Initiatives and AHA

Professional education initiatives allow doctors and other healthcare profession-

als to take research from bench to bedside and improve care for patients throughout America. The association provides the latest in scientific information through conferences, online training tools, satellite broadcasts and ten scientific journals. The association is also working hard to help hospitals in local communities improve protocols to provide better care for patients.

The American Heart Association is the recognised leader in CPR training and

has a nationwide network of instructors to train doctors, nurses and paramedics in how to provide life support for cardiovascular emergency victims. The association also works with companies, schools and the public to teach people how to handle cardiac emergencies. Finally, advocacy efforts at the local, state and national levels help legislators understand health issues and pass legislation that safeguards the cardiovascular health of Americans of all ages. ■

“Ten Nobel Prizes have been awarded to researchers for work funded by the American Heart Association”

*continued from page 21*

relate directly to the type of patient group served by the hospital (community hospital Vs. specialised referral centre), offered medical services (cardiac surgery or organ transplantation), or the quality of care provided. In addition to that, USPs can also relate to aspects of process affecting all products such as a special means of nursing, the implementation of a quality assurance program or a particularly innovative means of electronically archiving medical patient data.

USPs should be designed to be as defensible as possible. Thus, USPs which can easily be copied by a competitor are of considerably less value than those, which will remain truly unique preferably over a very long period of time. But differently, Unique Selling Proposals should be associated with 'high barriers of entry' for any potential competitor.

For a University Medical Centre (UMC) the following USPs seem to bear relevance: All products requiring an interdisciplinary approach: Since UMCs will generally be home to more sub-specialists than any other hospital, diseases requiring a multidisciplinary approach will be treated in a more efficient manner.

Complex diseases requiring intensive care: Since UMCs are generally equipped

with vast intensive care resources, they should be used for the treatment for the most complex disease entities requiring such services. Ability to adapt to new therapies: Since UMCs encompass research as well as medical care, it should be far easier to implement new medical advances in health care products.

Once defined, the USPs should be checked against those products, which have been determined to be both of high quality and high profitability. At the end, only those products combining defensible USPs with high medical quality and profitability should be further developed and entered into a future product portfolio.

Take home points:

- USPs can relate to various aspects defining the character, infrastructure or medical abilities of a hospital.
- Defensible USPs are those associated with high barriers of entry for any direct competitor.

Sales Strategies

Once a product portfolio has been defined, the hospital infrastructure has to be developed in a manner that strengthens the ability to deliver these products at maximal quality in minimal cost. These efforts should be made transparent to the customer by publishing them on the web. Furthermore,

these efforts must provide the basis for any direct sales strategy which, in analogy to all other industries, can only be based on quality and pricing. In this regard it will be most important to provide transparency regarding the definition of quality. Clearly, these aspects will need to be regulated in a homogeneous, hopefully European manner.

Take home points:

- Any sales strategy must be based on transparency regarding the quality and pricing of the medical products offered.
- Attention must be paid to existing laws and regulations governing the healthcare sector.

Summary

Healthcare is rapidly evolving from a totally non-transparent and heavily process-regulated system to a competitive market. To survive in such a market, hospitals will require the conscious development of marketing and sales strategies. These should be based on a product portfolio defined by quality, profitability and USPs. The bases of marketing and sales strategies must, however, lie in providing transparency to the customer, i.e. the patient, regarding outcome quality and pricing of healthcare products. ■

*continued from page 29*

also echocardiographers, intensive care specialists and functional clinicians.

Primary Prevention

For years, cardiology has focused primarily on treatment via drugs and interventions, but now the focus is turning more towards prevention, especially primary prevention.

In order to participate in this initiative, the Latvian Society of Cardiology delivers different educational programmes for society using mass media. For example, we coordinated different advertisements on TV and radio with information about dislipidemia, smoking, overweight issues, and hypertension as risk factors for cardiovas-

cular disease to educate the public.

Also, we have developed "heart health" rooms in outpatient clinics, where patients can come and measure their blood pressure, cholesterol levels as well as get specialist consultations. We have introduced programmes that promote heart health in

school children. We have measured body weight and blood cholesterol levels in children in schools and promoted healthy diet and physical activity to raise awareness amongst the next generation.

## Conclusions

Cardiology has changed dramatically in the last two decades, the result of which

is a trend in decrease of cardiovascular mortality and morbidity. We have achieved enormous progress in interventional cardiology ensuring large volumes of coronary interventions maintaining quality, which always have been our priority. Our cardiologists, primary care specialists and finally our society is reasonably better educated than a few years ago. ■

*continued from page 27*

safety of apixaban in patients (n = 1,715) with recent ACS is ongoing.

## Rivaroxaban

### Pharmacology

Rivaroxaban is an oral, direct FXa inhibitor that effectively inhibits free FXa activity, prothrombinase-bound and clot-associated FXa activity. Rivaroxaban has predictable dose-dependent pharmacokinetics and pharmacodynamics.

### Clinical trials

An extensive phase II programme indicated that rivaroxaban can be given to patients without dose modification for age, weight, gender and mild to moderate renal impairment. Results from these studies showed that total VTE (the composite of any DVT, non-fatal PE and all-cause mortality) occurred in significantly fewer patients receiving the rivaroxaban regimens compared with those receiving the enoxaparin regimens with similar rates of major bleeding.

When compared to the US regimen of enoxaparin (30 mg bid starting 12 - 24 hours after wound closure) rivaroxaban had superior efficacy for the prevention of VTE after TKR, without significantly increasing the risk of bleeding. The phase II and phase III programmes

also include studies evaluating rivaroxaban for VTE treatment (EINSTEIN DVT and EINSTEIN PE), long-term prevention of recurrent symptomatic VTE (EINSTEIN EXT), VTE prevention in medically ill patients (MAGELLAN), and the prevention of stroke in patients with AF (ROCKET AF).

Finally, the ATLAS ACS TIMI 46 phase II dose-finding study is evaluating rivaroxaban in patients with ACS treated with acetylsalicylic acid (ASA) alone or ASA + thienopyridine.

Rivaroxaban has recently received approval in Canada and the EU for the prevention of VTE in patients undergoing elective THR or TKR surgery.

### Implications for Management of Cardiovascular Conditions

These new anticoagulants may change the therapeutic approach to treatment and prevention of VTE. LMWHs require parenteral administration and are usually bridged to oral warfarin for long-term outpatient therapy. With oral anticoagulants, VTE prophylaxis after surgery could be initiated orally and patients could be discharged on the same oral medication, avoiding the need for self-injection or nurse visits for drug administration.

AF is a major risk factor for stroke. Currently, ASA and VKAs are the only available antithrombotics for stroke prevention in AF. Long-term stroke prevention with the new oral anticoagulants could potentially be more convenient for the patient. Furthermore, an oral anticoagulant that can be taken in a fixed, once-daily, dose with no need for monitoring might offer significant potential in the management of stroke prevention in AF.

Cost analyses suggest that anticoagulation is most effective and results in the greatest overall cost savings when applied to populations at highest risk for thrombotic events.

Preliminary analyses suggest that significant savings might be realised from oral administration compared with drugs administered parenterally that also require self-injection or nurse visits following discharge. Anticoagulants that offer greater efficacy or safety than current standards of care might achieve further cost savings due to a reduced incidence of thromboembolic events or haemorrhages, and corresponding reductions in recurrence and long-term complications. ■

## **CV Therapeutics Announces License Agreement**

The Menari Group have been granted exclusive rights to Ranexa. The agreement grants rights to Menarini for Ranexa in 68 countries, including the 27 countries of the European Union, the Commonwealth of Independent States and certain countries in Central and South America. The deal included an upfront pay

ment of 70 million dollars and further payments could amount to 315 million dollars.

Ranexa will be launched to specialists and primary care physicians. It is approved for use in Europe as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to firstline antianginal therapies.

## **EU Approves New Treatment**

Tracleer®, a dual endothelin receptor antagonist has been approved in the European Union for the treatment of patients with mildly symptomatic pulmonary arterial hypertension (WHO FC II). A clinical study of

patients with mildly symptomatic WHO FC II led to approval and revealed that even patients with mild symptoms are at risk of rapid deterioration. Tracleer delays disease progression in these patients and Actelion communicates these findings to encourage early diagnosis and intervention.

## **BIOTRONIK Home Monitoring Approved in Europe**

BIOTRONIK's wireless remote monitoring technology for patients with cardiac devices has been approved in Europe. It identifies patients with the most clinically relevant events to streamline clinic workflow and improve patient care. The traffic-light

severity-based display of patients' status identifies the most important information with one click and allows the review of the clinical status of patients. It provides one continuously updated and consolidated online CardioReport, easy-to-read clinical information, heart failure and atrial fibrillation diagnostics and intracardiac electrograms.

## **TeraRecon Releases New Device**

TeraRecon has announced the release of new innovations in its flagship Aquarius iNtuition™ platform. Showcased in September at the ASNC annual meeting in Boston, this client server aims

to improve efficiency within cardiac imaging. The new device is said to improve speed and accuracy in CT technology. It is workflow orientated, "available anywhere" through the healthcare enterprise and integrates with cardiology PACS solutions.

## **Anticlotting Medicine Lowers Incidence of Heart Attack**

New data shows anticlotting medicine Tirofiban (AGGRAS-TAT®) lowers incidence of heart attack in patients who respond poorly to aspirin or Clopidogrel after elective coronary angio-

plasty. Dr Marco Valgimigli, Chair of Cardiology, University of Ferrara, Italy and the principal investigator of the study emphasised the significance of the findings as they "Demonstrate a proof of concept for a new treatment strategy in a patient segment whose needs have so far remained unaddressed."

## **Physio-Control Receives FDA Clearance For LIFEPAK 20e Defibrillator/Monitor within the US**

Physio-Control, a wholly owned subsidiary of Medtronic Inc. received clearance from the FDA on October 3, 2008 to market the LIFEPAK 20e defibrillator

/monitor within the US. It is an enhancement of the LIFEPAK 20 with a more powerful lithium-ion battery doubling ECG monitoring time. It is a non-evasive way to monitor the oxygenisation of a patient's haemoglobin and has been developed so it can be easily transported helping hospitals meet JCAHO standards for having resuscitation services readily available in all facility areas.

## **Pfizer Research Reshuffle**

The Wall Street Journal has reported that Pfizer have abandoned the development of medicines for heart diseases. In the past Pfizer dominated the cardiovascular drugs sector with Lipitor being named as the worlds

best selling drug in 2007. Due to a reorganisation of research they will be leaving drugs such as Lipitor to focus on other programmes including oncology and Alzheimers. They have however confirmed that heart medicine development will continue but only with drugs in late-stage testing.



**Radi Medical Systems Inc. Announces Clearance of PressureWire Certus**

Previously only cleared for use in the coronary and peripheral blood vessels, PressureWire Certus can now be used to assess pressure measurements

across heart valves and into various chambers of the heart. It can also be used in the assessment of Fractional Flow Reserve (FFR). FFR expresses the maximum achievable blood flow in a coronary artery with abnormal stenosis as a fraction of maximum blood flow in the absence of a stenosis.

**St Jude Medical Announce Clearance of Implantable Device**

The SJM Confirm™ implantable cardiac monitor (ICM) is a compact device designed to help physicians detect abnormal heart rhythms in patients with unexplained symptoms. It enables the evaluation of heart rhythm signals over a longer period of time compared to standard monitoring tests and it is the smallest ICM available which can be

implanted in an outpatient procedure under local anaesthetic.

Patients can remotely send data when they experience symptoms therefore helping to diagnose and document difficult to detect rhythm disorders in patients who experience unexplained symptoms such as syncope, palpitations and shortness of breath. This product was developed in response to physicians need for more info about heart rhythm abnormalities.

**CYPHER Sirolimus-Eluting Coronary Stent Comparable to Bypass Surgery**

Cordis have released clinical data indicating that percutaneous coronary intervention with the CYPHER sirolimus-eluting coronary stent is comparable to bypass surgery in key safety measures in patients with diabetes and multi-vessel disease.

The data was recently presented at the European Society of Cardiology meeting. It is the only drug-eluting stent with such randomised clinical data indicating that it is comparable to bypass surgery for these specific patients. The study showed that after one year no difference from bypass surgery in terms of death, heart attacks or stroke was found. The trial was conducted at 24 medical centres throughout the UK and Ireland.

**University of Florida Medical Centre Install Toshiba Aquilion ONE Dynamic Volume CT**

Shands HealthCare at the University of Florida medical centre have installed the Toshiba Aquilion ONE dynamic volume CT. This may change the way hospitals and physicians treat and diagnose patients with cardiovascular and neurological disease. Aquilion ONE can perform single heart beat studies and capture organ perfusion,

actions that cannot be performed by other systems.

The system uses 320 ultra-high resolution detector rows (0.5 mm in width) to image an entire organ in a single gantry rotation. It shows up to 16cm of anatomical coverage and has many dynamic functions such as 4D clinical video. Toshiba maintain that with Aquilion ONE, a single exam may provide physicians with data to replace a variety of duplicative tests and invasive procedures.

**Philips and Steris Alliance to Provide Hybrid Surgical Rooms**

These hybrid surgical rooms will provide optimal imaging during open and minimally invasive cardiovascular surgical procedures in a bid to enhance workflow. The combination of Philips

cardiovascular x-ray systems and Steris HD 360 suites technologies and design service aims to create a flexible treatment environment in a single suite. It will in turn provide hospitals with opportunities for surgical innovation and improved infection prevention programmes.

**Trials Show CRT Delays First Hospitalisation**

Medtronic sponsored trials by REVERSE and PARTNERS HF have shown that cardiac resynchronisation therapy (CRT) delays the time to the first hospitalisation or death in patients with mild heart failure, and devices equipped with OptiVol® Fluid Status Monitoring identified patients who were at a significantly higher risk of having

heart failure events in the near future. Although normally for patients with moderate or severe heart failure this research has shown that CRT has significant benefits for patients with mild heart failure, helping to prevent the progression of the condition. Similarly, the continuous device monitoring of heart failure patients in addition to periodic office visits can identify patients at increased risk of heart failure and allow for early intervention.

## Key Seminars and Conferences

### DECEMBER 2008

- 10 - 13 **EuroEcho 2008**  
Lyon, France  
[www.escardio.org/congresses/euroecho2008/Pages/welcome.aspx](http://www.escardio.org/congresses/euroecho2008/Pages/welcome.aspx)
- 13 - 16 **69th Annual Congress of the Italian Society of Cardiology**  
Rome, Italy  
[www.sicardiologia.it](http://www.sicardiologia.it)

### JANUARY 2009

- 14 - 17 **Annual Meeting of the French Cardiology Society**  
Paris, France  
[www.sfcadio.fr](http://www.sfcadio.fr)
- 29 - 31 **28th Annual Meeting of the Belgian Society of Cardiology**  
Brussels, Belgium  
[www.bsccardio.be](http://www.bsccardio.be)

### FEBRUARY 2009

- 20 - 22 **CardioRhythm 2009**  
Hong Kong, China  
[www.cardiorhythm.com](http://www.cardiorhythm.com)

### MARCH 2009

- 29 - 31 **58th Annual Scientific Session of the American College of Cardiology**  
Orlando, Florida  
[www.acc.org](http://www.acc.org)

### APRIL 2009

- 16 - 18 **75th Annual Meeting of the German Cardiology Society**  
Mannheim, Germany  
[www.dgk.org](http://www.dgk.org)
- 18 - 22 **Annual Congress of the Portuguese Society of Cardiology**  
Vilamoura, Portugal  
[www.escardio.org/membership/national-societies/Portugal/Pages/welcome.aspx](http://www.escardio.org/membership/national-societies/Portugal/Pages/welcome.aspx)
- 22 - 23 **56th Annual Conference of the Israel Heart Society**  
Tel-Aviv, Israel  
[www.israel-heart.org.il/Congresses1.asp](http://www.israel-heart.org.il/Congresses1.asp)
- 24 - 25 **9th Annual Spring Meeting on Cardiovascular Nursing**  
Dublin, Ireland  
[www.escardio.org/congresses/cardio-nursing-conference/Pages/welcome.aspx](http://www.escardio.org/congresses/cardio-nursing-conference/Pages/welcome.aspx)

### MAY 2009

- 6 - 9 **EuroPREvent 2009**  
Stockholm, Sweden  
[www.escardio.org/congresses/europrevent-2009/Pages/welcome.aspx](http://www.escardio.org/congresses/europrevent-2009/Pages/welcome.aspx)
- 10 - 13 **Nuclear Cardiology and Cardiac CT Meeting**  
Barcelona, Spain  
[www.icnc9.org](http://www.icnc9.org)
- 30 - 2 **Heart Failure Congress**  
Nice, France  
[www.escardio.org/congresses/HF2009/Pages/HeartFailureCongress2009.aspx](http://www.escardio.org/congresses/HF2009/Pages/HeartFailureCongress2009.aspx)

### JUNE 2009

- 21 - 24 **EuroPACE 2009**  
Berlin, Germany  
[www.escardio.org/congresses/EUROPACE2009/Pages/welcome.aspx](http://www.escardio.org/congresses/EUROPACE2009/Pages/welcome.aspx)

**Cardiology Management**  
28/7, rue de la Loi  
B-1040 Bruxelles, Belgium  
T: +32/2/ 286 85 00  
F: +32/2/ 286 85 08  
[www.cardiologymanagement.eu](http://www.cardiologymanagement.eu)

**Publisher**  
Christian Marolt  
[c.m@cardiologymanagement.eu](mailto:c.m@cardiologymanagement.eu)

**Editor-in-Chief**  
Prof. Panos Vardas  
[vic@cardiologymanagement.eu](mailto:vic@cardiologymanagement.eu)

**Managing Editor**  
Dervla Gleeson  
[edi.torial@cardiologymanagement.eu](mailto:edi.torial@cardiologymanagement.eu)

**International Editor**  
Edward Susman  
[ed@cardiologymanagement.eu](mailto:ed@cardiologymanagement.eu)

**Editors**  
Helicia Herman  
Caroline Hommez  
Ana Gabriela Felix  
Lee Campbell

**Guest Authors**  
Prof. C. Bekes  
Dr. G. Cappellaro  
Dr. M. Cobble  
Prof. G. De Keulenaer  
Prof. A. Erglis  
Prof. R. Ferrari  
Prof. M. Goyen  
M. Karamalis  
J. Launders  
Prof. S. Rajaram  
Dr. L. Ruhmann  
Prof. L. Rydén  
Prof. A. Turpie

**Global Communications**  
Dr Don I. Idrees  
[d.i@cardiologymanagement.eu](mailto:d.i@cardiologymanagement.eu)

**Journal Management**  
Katya Mitreva  
[office@cardiologymanagement.eu](mailto:office@cardiologymanagement.eu)

**Creative Director**  
Sabine Sehringer

**Production and Printing**  
PPS, Print run: 12,000  
ISSN = 1784-6331



#### Verified Circulation

according to the standards of International Business Press Audits

Cardiology Management is independently audited by Accountskantoor Closset

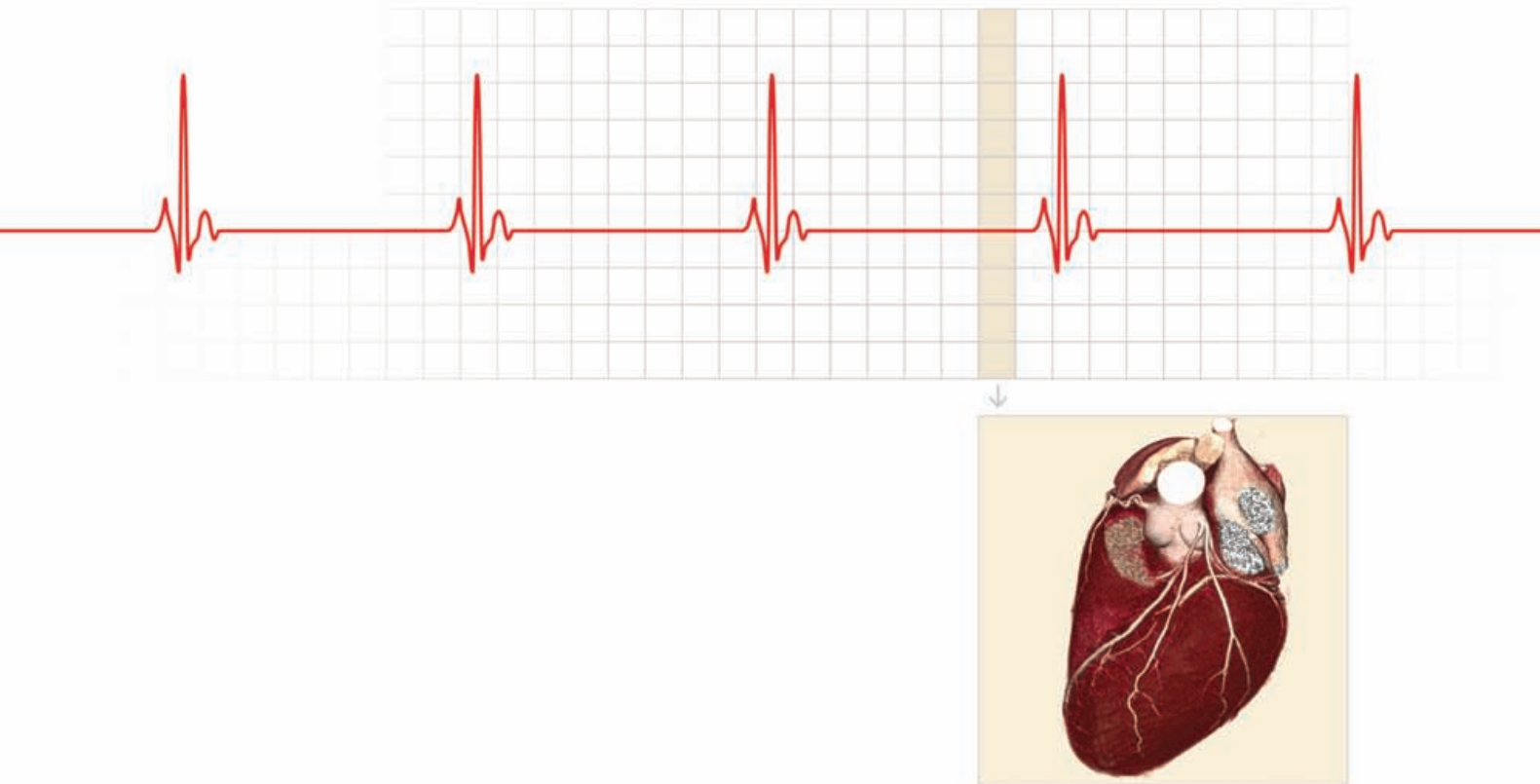


## **EMC Consulting - Your Gateway to European Healthcare Management Consulting**

- Strategic healthcare management consulting
- E-Health and education
- Media, public relations and communications
- Event Cocooning
- Congress and conference participation
- Association representation and lobbying
- EU project communications

# TOSHIBA

Leading Innovation >>>



## One beat cardiac imaging

Aquilion ONE: the world's first dynamic volume CT



Toshiba Medical System's Aquilion ONE is a quantum leap in CT imaging that can capture a 3D image of the heart in just one beat.

The wide coverage provided by the Aquilion ONE's 16cm detector, which has 320 detector rows, can scan the brain or heart in less than a second. So you can see an entire organ in 3D with perfect continuity along the z-axis. Or see it in 4D, moving as time passes. Or see it extremely fast, with a lower contrast medium dose and exposure dose.

The Aquilion ONE will bring you dynamic views of the body you could not see before.

See it for yourself at [www.toshiba-medical.eu](http://www.toshiba-medical.eu)

**ONE**  
*Aquilion*

Toshiba: Made for Patients, Made for You, Made for Life!



ULTRASOUND **CT** MRI X-RAY SERVICES