## CARDIOLOGY MANAGEMENT

Volume 2 - Issue 1, Spring 2008

## ESC Guidelines & Their Implementation

- Cardiology PACS
- Remote Monitoring
- Cardiology Management in Greece





FROM PATIENTS TO POPULATIONS

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#### Editorial

Dear Readers,

Medical science in practice has always been closely dependent on prevailing economic, social, and cultural conditions. This was true in ancient times and has remained true until the present day. Never before, though, has that science shown such rapid advances, while at the same time being so crucially tied to costs, priorities, and political choices. Inevitably, therefore, the rational management of healthcare services has become a goal of major importance.

Management itself, in theory and in practice, has a multi-factorial character, in which many, often disparate, components act synergistically towards the realisation of a strategic objective. When the latter is healthcare—whether it be prevention or the treatment of disease—it is evident that management plays a much more complex role and that managers must combine fiscal rationality with the higher value represented by the uniqueness of each individual life.

Indeed, Hippocratic medicine lays down the non-negotiable principle that the physician must constantly and unswervingly choose what is best for the patient. Fortunately, this premise continues to hold sway as a central perception in the philosophical core of modern medicine and to oversee the swearing in of new doctors all around the world. Its official repudiation, even in a limited way, would have huge repercussions with respect to the anthropocentric focus that our civilisations and religions have maintained for centuries.

However, the idealistic Hippocratic approach has recently fallen on hard times, in the light of the reality imposed by the increase in healthcare costs. Medicine has long since ceased to be a game of solitaire and has become a multi-player game in which other participants, not the physician, may shuffle, deal, and set trumps. The complexity of the factors that determine costs, the questioning of the result of each and every priority within the sphere of healthcare, have created a need for rational management. The task sounds reasonable, even easy; but it is not. If the financial management of healthcare and the priorities for human and economic resources were the simple result of logic, there would not be so many alterations, altercations, publications, and not infrequently, calamities.

This Journal will be published quarterly, with a well-defined purpose: to present, primarily to cardiologists and secondarily to hospital managers, a spectrum of topics related to evidence-based cardiology, such as guidelines, the affordability to caregivers of their implementation, patients' access to medical technologies, management of available resources, and of course, matters pertaining to daily nosocomial reality.

Cardiovascular medicine has had many successes in recent years, but there are also practical necessities. One voice, we hope a strong one, from this publication can surely make a positive contribution to the rationality of all kinds of decision making. In this effort it is our hope and wish that we will have your support.

Yours faithfully,

Panos E. Vardas, MD, PhD Professor of Cardiology



Professor Panos Vardas



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## CARDIOLOGY MANAGEMENT

#### SEVENTH FRAMEWORK PROGRAMME FOR RESEARCH AND TECHNOLOGICAL DEVELOPMENT

Research a Top Priority for the European Commission

AUTHOR

Dervla Gleeson Managing Editor

#### How is FP7 Made Up?

FP7 is made up of four main specific programmes under the headings Cooperation, Ideas, People and Capacities, plus a fifth specific programme on nuclear research. Here we assess the most relevant ones.

#### Cooperation

With a budget of €32 billion, the "Cooperation" programme will provide research support to international cooperation projects across the European Union and beyond. Its ten thematic areas, corresponding to major fields in science and research will promote the progress of knowledge and technology. Research will be supported and strengthened to address European social, economic, environmental, public health and industrial challenges, serve the public good and support developing countries.

#### **Health Research Programme**

With a budget of €6 billion, the health research programme aims to improve the health of European citizens, and increase and strengthen the competitiveness and innovative capacity of European healthrelated industries and businesses. Global health issues, like emerging epidemics, will also be addressed. European collaboration with developing countries will allow those countries to develop research capacities. Its emphasis will be put on translational research (i.e. the translation of basic discoveries in clinical applicaThe Seventh Framework Programme for Research and Technological Development (FP7) is the European Union's (EU) main instrument for funding research in Europe. Running from 2007 to 2013, it will execute a budget during that period of €50.5 billion and an additional Euratom budget for the next five years of €2.7 billion. FP7 is designed to support research in selected priority areas.

tions), the development and validation of new therapies, methods for health promotion and prevention including the promotion of healthy ageing, diagnostic tools and medical technologies, and sustainable and efficient healthcare systems.

Clinical research will tackle a number of diseases such as cancer, cardiovascular, infectious, mental and neurological diseases, and in particular those linked with ageing, such as Alzheimer's and Parkinson's diseases. Through international multi-centre trials involving the required number of patients, new drugs and treatments would be developed in a shorter time frame. European-funded health research will focus on;

- · Biotechnology, generic tools and medical technologies for human health;
- High-throughput research;
- Detection, diagnosis and monitoring;
- Prediction of suitability, safety and efficacy of therapies;
- Innovative therapeutic approaches and intervention;
- Translating research for human health;
- Integration of biological data and processes:
- Research on the brain and related diseases, human development and ageing;
- Translational research in infectious diseases (HIV/AIDS, malaria, tuberculosis, SARS, avian influenza);

- Translational research in major diseases: cancer, cardiovascular disease, diabetes/obesity, rare diseases, other chronic diseases including rheumatoid diseases, arthritis and musculoskeletal diseases;
- Optimising the delivery of healthcare to European citizens;
- Translation of clinical outcome into clinical practice;
- Quality, efficiency and solidarity of healthcare systems including transitional healthcare systems and home care strategies;
- Enhanced disease prevention and better use of medicines, and
- Appropriate use of new health therapies and technologies.

#### "People" Programme Supports **Careers in Research**

With a budget of €4.7 billion, the "People" programme offers individuals training and career development in research. It aims to encourage European researchers to stay in Europe and attract the best researchers in the world to European research excellence and infrastructures. The "People" programme should encourage individuals to enter the profession of researcher; structure their research training by offering options; and, encourage mobility within the same sector. The mobility of researchers is not only key to the career development of

researchers but also vital to the sharing and transfer of knowledge between countries and sectors.

During FP7 a series of EU research funded actions will support the on-going training, research and mobility of highly qualified scientists and encourage the proliferation of centres of excellence in the EU and their contribution in new areas of research and technology. This will be carried out through initiatives such as lifelong training and career development through individual fellowships and cofinancing programmes at international, national and regional level and international outgoing and incoming fellowships aiming to increase research talent outside Europe and fostering mutually beneficial research collaboration with researchers from outside Europe. The activity will also include measures to counterbalance "brain drain" and create networks of European researchers working abroad.

#### **Capacities**

With a budget of €4.2 billion, the "Capacities" programme will optimise

the use and development of research infrastructures, while enhancing the innovative capacities of SMEs to benefit from research. The programme is designed to support regional research-driven clusters and at the same time unlock the research potential in the EU's convergence and outermost regions.

#### Four Countries Sign Agreement to Join FP7

Croatia, Serbia, the former Yugoslav Republic of Macedonia and Turkey all recently signed agreements that enable their eligibility to compete on an equal footing with EU Member States in the Seventh Framework Programme (FP7), following the signature of Memoranda of Understanding with the European Commission.

These countries will now be able to participate in all the FP7 calls for proposals and enjoy the same rights for participation as EU Member States in all the research cooperation and supported actions funded under FP7.

Science and Research Commissioner

Janez Potocnik has noted the importance of the agreement in view of these countries' application to join the EU. 'Research cooperation with Europe's scientific community is a tool which can smooth the way for the integration process of candidate and potential candidate countries into the European Union,' he said.

Montenegro has also requested to become associated with FP7 and it is expected that a decision will be taken once Stabilisation and Association Agreement (SAA) negotiations have come to a head. Albania, Bosnia-Herzegovina, Israel and Switzerland are also expected to join soon.

#### **Further Reading**

http://cordis.europa.eu/fp7 http://www.dti.gov.uk/science/ uk-intl-engagement/euro-programmes/ fp7/page38886.html http://europa.eu/scadplus/leg/en/lvb/i23 022.htm

#### EUROPEAN SUMMIT ON CARDIO-VASCULAR DISEASE PREVENTION

"Bridging the unacceptable gap between what is recommended and what is achieved in daily practice regarding the prevention of cardiovascular disease" is how Prof Guy De Backer, Chairman of the CVD Prevention Committee of the European Society of Cardiology (ESC), summarises the aim of the European Summit on Cardiovascular Disease Prevention.

Creating incentives for people to make healthy choices in every European country is the difficult task that the 200 delegates of 46 countries and 27 health organisations have undertaken at the European Summit on Cardiovascular Prevention. The meeting took place at the Heart House, headquarters of the ESC, Sophia-Antipolis, France.

Cardiovascular disease (CVD) causes 49% of deaths in Europe, is the main cause of death in women on this continent and costs the EU over €169 billion a year. Getting countries to educate their population and allocating an adequate budget to preventive care and rehabilitation is therefore of the utmost importance.

By the end of 2008 all European countries will have subscribed to the European Heart Health Charter (www.heartcharter.eu) and will have set up a Joint National Task Force to take the necessary actions to implement it. The Fourth European Task Force recently published Guidelines for the Prevention of CVD, which are the result of a unique consensus between

experts of different specialties. These guidelines must now be translated and implemented locally, taking into consideration national, cultural and socioeconomic issues.

Schools, hospitals and policy makers are being encouraged to increase their efforts to educate people on the basics of heart disease prevention which include a balanced diet, physical activity and avoidance of tobacco. Actions which lead to the reimbursement of CVD prevention within existing healthcare and private insurance plans are also being encouraged by countries and organisations attending the European Summit.

## 6 CARDIOLOGY MANAGEMENT

#### **ESC GUIDELINES**

#### Expanding Implementation Strategies in Europe



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Nobody will argue against the usefulness of the European Society of Cardiology's (ESC) guidelines. Firstly, it is acknowledged worldwide that ESC guidelines have a great scientific value. Secondly, following these recommendations saves patient lives, which is our ultimate goal. The ESC also has a unique structure, which provides the opportunity to produce good documents. Guidelines are now a core activity for the ESC, and the guidelines committee interacts with other available structures within the ESC. Guidelines are derived from the results of research and clinical trials, and they also generate education through the education committee. Finally, their efficacy is then scrutinised by the Euro Heart Survey.

The cornerstone of ESC guidelines is teamwork, as their generation involves the close cooperation of all the constituents of the ESC. They are edited under the umbrella of the board, which solicits the involvement of working groups, associations and national societies for the production and implementation of guidelines. Harmonising so many different views is a challenge, but it has many advantages since different backgrounds provide balanced views from experts who are not just sub-specialists. The final product takes advantage of this varied expertise to achieve the appropriate methodology, homogeneity and consistency in its message.

#### How are Guidelines Generated?

The ESC has produced more than thirty different documents since 2001, covering over 85% of the core syllabus, as well as providing updates on a regular basis. The Clinical Practice Guidelines (CPG) committee is responsible for the selection of topics, the coordination of the writing and review processes, and final approval before publication. It is composed of members from many different national societies as well as associations and working groups.

The CPG works very closely with taskforce members. Here again, the composition of taskforces should represent a good balance of different nations, working groups and sub-specialties. These members are chosen according to their expertise and representativeness. There, independence from industry is clearly stated in a declaration of conflicts of interest. The same should also be true for the reviewers.

#### Focus on Good Quality a Future Goal

Our first goal for the future is to continue this production of good quality documents.

The recipe for good documents is nicely

summarised in a message delivered by Michal Tendera, the Past-President of the ESC, who says that in order to be implemented, guidelines must be universal, coherent and credible, and it is very important to avoid any bias. These guidelines must be easy to understand and applicable. Guidelines reflect the best knowledge we have from trials, etc, however, they should be less focused on describing results and more focused on practice options. Finally, we should always have in mind that guidelines help in the management of our patients but should be used as a supplement to and not instead of good clinical judgement.

Our second main goal is to improve implementation, as it is pointless to have a good product and not to use it! If we look at real life, there is a gap between guidelines and practice as shown by the Euro Heart Survey. Why do we not follow guidelines in practice? Generally speaking, cardiologists may remark on the proliferation of guidelines worldwide, as well as their being too complex, too long, irrelevant for our patients, impractical or even impossible to use.

#### Improving Implementation

There are several steps that could be followed to improve the implementation of guidelines. During the annual ESC congress the presence of guidelines could be improved by involving them in "Meet the Expert" sessions. Guidelines sessions could also form part of the programme at association meetings. We should also aim to hold guideline implementation courses. National societies are key players in the lifeblood of guidelines. Naturally, they participate in the elaboration of guidelines through the participation of their members in the working groups and

associations, but they also have a pivotal role in their implementation. These steps for endorsement and implementation have been set up through several SOPs, which are accessible on the ESC website. The first step is the endorsement and translation of the guidelines by the national societies.

The national society may endorse and adapt guidelines, meaning that the document may be translated, annotated and implemented. Good translation is a key issue for publication. This mutual enrichment is the key to success and requires good communication.

#### Dissemination the Key to Awareness

Our challenge is to encourage dissemination to the widest possible professional readership. Guidelines are published in the family of journals of sub-specialties within the ESC, a key way to publish the full text given that the Euro Heart Journal only publishes the executive summary. In addition, the 35 national journals within the ESC represent a fantastic driving force for dissemination. A fasttrack procedure has now been adopted by several countries such as Spain, Greece, and Poland, a list that should keep growing. In this respect, we are very happy to see the initiatives taken under the umbrella of the new editors club.

National societies can also be useful in the implementation of guidelines through the organisation of meetings. During the national meetings, dedicated guidelines sessions organised in partnership with the ESC, highlights or more specific sessions would help as well as interactive sessions, or «Guidelines Versus Practice» sessions. The national society may also organise specific implementation meetings and courses with national experts and taskforce members, to go through the main points and engage in a constructive discussion.

Another important point in the implementation of guidelines is to improve the tools we have for their dissemination. In addition to the publication in the European Heart Journal, there is also a vast armamentarium of increasingly popular derivative products, such as pocket guidelines, compendiums of these pocket versions, PDA versions, and educational slide sets, etc. The internet is the preferred vector for the dissemination of guidelines. The number of hits to the site show just how successful it is. The PDA pocket guidelines are also very successful with more than 100,000 transfers. The site is being modified in order to make it user friendly, and links to the national sites are particularly important.

Dissemination is clearly crucial, however, it is also paramount to follow up the quality of this dissemination through audits. Here again we have tools available with the Euro Heart Survey. In the hospitals themselves we can develop feedback tools as well as give feedback on the adherence to guidelines. This feedback system will even transform simple data collection into dedicated studies with educational consequences. An example of this exists in Ludwigshafen and could be disseminated.

Finally, the links between guidelines and education are obvious. The guidelines may well serve as a platform for building the educational material used at a European level to obtain accreditation and revalidation. Clearly, we have a large armamentarium of methods to pass on the message.

#### ARE ESC SYNCOPE GUIDELINES **BEING IMPLEMENTED IN EUROPE?**

#### A Picture from the Real World



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The utilisation of medical resources and the expenses associated with syncope management are enormous. Assuming the status quo of syncope evaluation is left in its present state, the effectiveness of diagnosis and treatment is unlikely to substantially improve. Even implementation of the published syncope management guidelines is likely to be diverse, uneven in application, and of uncertain benefit. Guidelines from scientific societies should provide the standard, but are poorly known and sometimes difficult to apply in clinical practice. Also, physicians from specialties different to those that created the guidelines are reluctant to apply it to their patients. Thus, guidelines alone will hardly change standard practice.

A prospective, observational registry from a sample of 28 general hospitals was performed in Italy in order to evaluate the impact of the guidelines of the European Society of Cardiology (ESC) on the management of syncope admitted in emergency. The Evaluation of Guidelines in Syncope Study 1 (EGSYS-1) enrolled all consecutive patients referred to their emergency rooms from November 5, 2001 to December 7, 2001 who were Despite the implementation of several clinical guidelines, current strategies for the assessment of syncope vary widely among physicians and hospitals. Evaluation and treatment of syncope is often haphazard and unstratified. This results in the inappropriate use of diagnostic tests and in a number of misdiagnosed and still unexplained syncope.

affected by transient loss of consciousness as the principal symptom. The findings of each of the 28 hospitals participating in the survey were evaluated separately.

#### Study Fails to Identify Uniform Syncope Practices

The authors observed great inter-hospital inter-department heterogeneity regarding the incidence of emergency admission, in-hospital pathways, most of the examinations performed and the final diagnosis. For example, the execution of carotid sinus massage ranged from 0% in one hospital to 58% in another (median 12.5%) (see fig. 1); tilt testing ranged from 0% to 50% (median 5.8%) and the final diagnosis of neurally-mediated syn-

#### Carotid sinus massage by hospital

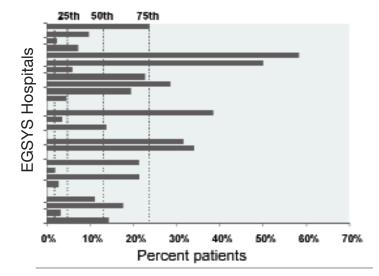


Fig. 1. Incidence of execution of carotid sinus massage (expressed as percentage of total patients admitted) among the 28 participating hospitals to EGSYS 1 study. Each bar represents one hospital. The vertical dotted lines are those corresponding to the 25th, 50th and 75th percentiles of distribution.

cope ranged from 10% to 78.6% (median 43.3%). As a consequence of the great inter-hospital variability, the authors were unable to describe a uniform strategy for the management of syncope.

This heterogeneity was minimally explained by a difference in the clinical characteristics of the population referred to by the hospitals participating in the study. Indeed, the proportion of explained variability was calculated to be less than 10% of total variance. Thus, we can assume that the main determinant of this different behaviour lies in the different attitudes of the staff.

The results of this study probably assessed the current standard for the management of syncope and provided a frame of reference for daily activity when dealing with syncope. As a consequence of these methodological features, the results markedly differed from those of previous investigations; more diagnosis of neurally-mediated syncope were made and much less syncope remained unexplained than in the past (see fig. 2).

A prospective, controlled, multi-centre study was performed in order to verify if this standardised method of care is feasible in the real world and superior to the usual care. The patients referred from compared with those of EGSYS-1 referred from November 5 to December 7, 2001 who were managed according to the usual practices. There were 929 patients in the usual care group and 745 patients in the standardised care group. The baseline characteristics of the two study populations were similar.

#### Study Underpins Guidelines

At the end of the evaluation, 78% of the patients assigned to the standardised care group adhered to the guideline-based evaluation achieving, when compared to usual care, 17% less hospitalisation rate (39% vs 47%), 11% shorter in-hospital

	Usual care	Standardised care	p value
	n=929	n=745	
Total costs (Euro):	1,295,000	839,449	
- hospital costs, %	1,005,202 (78%)	633,149 (75%)	
- costs for tests, %	289,789 (22%)	206,300 (25%)	
Cost per patient	1394±1850	1127±1383	0.0001
Cost per patient discharged from ER	180±63	180±75	0.88
Cost per patient hospitalised	2785±2168	2621±1878	0.001
Cost per diagnosis	1753±2326	1240±1521	0.0001
Cost per diagnosis per patient discharged from ER	226±79	198±83	0.001
Cost per diagnosis per patient hospitalised	3506±2729	2880±2064	0.0001

Table 1. Cost-Analysis Results for Implementation of ESC Guidelines in Italy

Therefore, what can one do? The solution is the creation of standardised care pathways in which guidelines can be effectively applied.

#### **New Strategy**

The Evaluation of Guidelines in Syncope Study 2 (EGSYS-2) validated a new method of management for syncope based on a decision-making approach developed in strict adherence to the recommendations of the updated guidelines of the ESC in 465 patients from 11 general hospitals. In order to maximise its application, a decision-making guideline-based software was used and trained core medical personnel were designated – both locally in each hospital and centrally – to verify adherence to the diagnostic pathway and give advice on its correction.

October 4 to November 5, 2004 for emergency care, to 19 Italian general hospitals were managed according to this new standardised care pathway and were stay (7.2±5.7 vs 8.1±5.9 days) and 26% fewer tests performed per patient (median 2.5 vs 3.4). Forty-one percent more standardised care patients had a diagno-

#### Causes of Loss of Consciousness - Secular Frend

Diagnosis	1980's*	2000's^^	2006***
Neurally-mediated & orthostatic	3/%	56%	/6%
Cardiac arrhythmias	13%	11%	11%
Structural cardio-pulmonary	4%	3%	5%
Non syncopal	10%	9%	6%
Unexplained	36%	20%	2%

- Data pooled from 6 population-based studies (1499 patients) (6,7,8,9,10,11)
- \*\* Data pooled from 4 population-based studies (1640 patients) (12,13,14,15)

" Data from EGSYS 2 study (465 patients) (4)

#### Cover Story ESC Guidelines & Their Implementation

sis of neurally-mediated (65% vs 46%) and 66% more of orthostatic (10% vs 6%) while 54% fewer had a diagnosis of pseudo-syncope (6% vs 13%) and 75% fewer of unexplained syncope (5% vs 20%) (see table 2). The mean cost per patient was 19% lower (1127 euros vs 1394 euros) and the mean cost per diagnosis was 29% lower (1240 euros vs 1753 euros) in the standardised care group (see table 1, page nine).

Thus, this study showed that a standardised care pathway significantly improved diagnostic yield and reduced hospital admissions, resource consumption and overall costs. Although the results of this study are difficult to reproduce in everyday practice, the study shows that ESC guidelines can be implemented in the clinical setting, provided the presence of trained medical personnel and the use of specifically designed decision-making software are in place. Thus, these results support the creation of cohesive, structured syncope facilities, as in the model proposed by the ESC guidelines in order to provide optimal quality service on the basis of well-defined, up-to-date diagnostic guidelines.

	Usual care n=929		Standardised n=745	care	
	Absolute no.	%	Absolute no.	%	p value
In-hospital pathway, number of patients:					
Discharged from ER	496	53%	456	61%	0.001
Hospitalised:	433	47%	289	39%	0.001
- Internal medicine/Geriatrics	273	29%	176	24%	0.008
- Cardiology	91	10%	75	10%	0.853
- Neurology	44	5%	8	1%	0.001
- Other wards	25	3%	30	4%	0.128
In-hospital stay (days±SD)	8.1±5.9		7.2±5.7		0.04
Tests performed, number of patients:					
Electrocardiogram	880	95%	745	100%	0.001
Basic laboratory tests	726	78%	263	35%	0.001
Echocardiogram	170	18%	120	16%	0.239
Tilt testing	60	6%	96	13%	0.001
Carotid sinus massage	130	14%	112	15%	0.548
Prolonged electrocardiographic	215	23%	84	11%	0.001
monitoring					
Exercise test	11	1%	23	3%	0.006
Electrophysiological study	19	2%	22	3%	0.232
Coronary angiography	14	2%	12	2%	0.865
Electroencephalography	112	12%	42	6%	0.001
Brain CT scan and/or MRI scan	182	20%	115	15%	0.027
Carotid echo-doppler	170	18%	33	4%	0.001
Chest x-ray	257	28%	87	12%	0.001
Abdominal echography	57	6%	18	2%	0.001
Miscellaneous (one or more test per patient)	184	20%	99	13%	0.001
Total number of tests(+)	3121		1912		
Median no. of tests per patient	3.4		2.6		
(interquartile range)	(3.1-4.0)		(2.1-3.0)		0.001
Final diagnosis (*), number of patients:	882		712		
Neurally-mediated	410	46%	466	65%	0.001
Orthostatic	54	6%	74	10%	0.002
Cardiac	112	13%	96	13%	0.644
Cerebrovascular	14	2%	0	0%	0.001
Syncope-like conditions (**)	115	13%	41	6%	0.001
Unexplained syncope	177	20%	35	5%	0.001
Diagnosis not available (incomplete records/evaluation)	47		33		
In-hospital mortality, number of patients	10	0.1%	6	0.08%	0.50

<sup>+</sup> Total number of tests is superior to the sum of single tests because some patients repeated the same test, and 1 miscellaneous test per patient was performed

<sup>\*</sup> According to the Classification of Loss of Consciousness of the Guidelines of the European Society of Cardiology (5)

\*\* Syncope-like conditions include: Metabolic disorders (hypoglycaemia, hypoxia, hyperventilation), Epilepsy, Intoxications, Transient ischaemic attack, Cataplexy, Drop attacks, and Psychogenic "syncope" (Somatisation disorders)

#### **HEART FAILURE GUIDELINES**



Problems of Heart Failure Therapy in Europe and Guidelines Implementation

A LITHOR

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Cardiology societies in Europe and the US have already addressed such a need by issuing regular updates of the Guidelines for Heart Failure Diagnosis and Treatment. The most recent update of the European Society of Cardiology (ESC) guidelines was published in 2005, and the task force is now finalising the new, comprehensive version, which will be presented at this year's ESC meeting in Munich. In this article, only selected aspects of pharmacological therapy will be briefly discussed.

#### Guidelines on Pharmacological Treatments

Recent ESC guidelines clearly state that four classes of drugs that target neuroendocrine activation, i.e. angiotensin-converting enzyme inhibitors (ACEi), angiotensin-receptor blockers (ARBs), beta-blockers and aldosterone antagonists reduce mortality and morbidity in HF.

#### **ACEi**

In general, patients should receive a combination of ACEi and beta-blockers, whose doses need to be up-titrated to either those levels recommended by the guidelines, or to the maximal level tolerated. This approach results in a reduction in mortality and morbidity and improvement in clinical status. Intolerance is rare, provided that patients are carefully followed and comprises for ACEi — cough, symptomatic hypotension, and renal dys-

As heart failure (HF) emerges as one of the key problems of modern cardiology, numerous articles are being published that report novel and intriguing results. The next step is to select findings with irrefutable clinical impact, based on large, randomised, clinical trials and to further implement them into clinical practice. Therefore, in order to help physicians treating HF patients, it is crucial to develop guidelines that are evidence-based and provide compelling information on how to select the optimal strategy for HF management.

function, and for beta-blockers – hypotension, bradycardia and worsening of HF.

#### **ARBs**

ARBs are recommended in symptomatic patients intolerant to ACEi, and can be considered in combination with ACEi and beta-blockers in patients who remain symptomatic to reduce cardiovascular mortality, hospital admissions and improve symptoms. Use of such triple combinations may cause hypotension and renal dysfunction and requires careful monitoring of blood chemistry.

#### Aldosterone antagonists

The guidelines recommend aldosterone antagonists in patients remaining in advanced HF (NYHA III-IV) in addition to ACEi, beta-blocker and diuretics, but whether they exert favourable effects in mild HF needs to be established. Renal dysfunction, hyperkalaemia and antiandrogenic effects for spironolactone (mainly gynaecomastia) are the main causes of intolerance. Monitoring of renal function and electrolytes is recommended once they are introduced into therapy.

#### **Diuretics**

Diuretics are essential when fluid overload is present. However, there are no controlled, randomised trials investigating whether diuretics affect patient outcome. Results of recently published studies raised concerns that high doses of diuretics may be related to impaired outcome. Digoxin is also commonly used in HF patients with concomitant atrial fibrillation and may reduce HF hospitalisations and improve symptoms.

#### Statins

The guidelines did not make any recommendation as to whether statins should be used in HF - when they were published, no data from randomised clinical trials existed. Only recently, the results of Controlled Rosuvastatin the Multinational Trial in Heart Failure (CORONA) has demonstrated that rosuvastatin does not reduce the primary composite outcome of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke or the number of deaths from any cause in older patients with systolic HF, although it reduces the number of cardiovascular hospitalisations.

There was no concern regarding the safety of rosuvastatin in HF. Translating these slightly surprising results into clinical practice, it seems acceptable to continue with statin prescription for patients with

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## 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

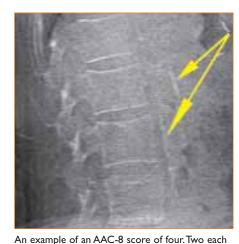
both strong and independent of the traditional cardiovascular risk factors, and this need is particularly acute in women. Abdominal aortic calcification (AAC), an indication of atherosclerosis, is significantly associated with both cardiovascular heart disease and stroke even after adjustment for the 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.

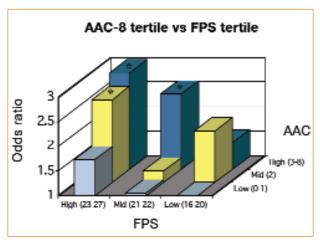
#### Detection of Abdominal Aortic Calcification with IVA

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.

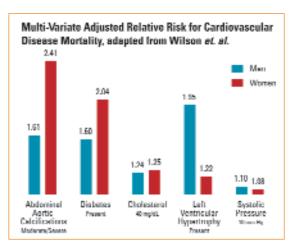
Because of the expected prevalence of vertebral fractures, IVA exams are most typically performed in women age 65 or older. This



on the anterior and posterior walls of the aorta.



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. IBMR 2008 Mar;23(3): 409-16.



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.

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 cal-cified 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 LI 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 posteriorwalls 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

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

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 IIfold 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.

## DescriptionScoreNo calcification seen0Aggregate length of calcification is $\leq$ to the height of one vertebra1Aggregate length of calcification is > one but $\leq$ two vertebra2Aggregate length of calcification is > two but $\leq$ three vertebra3Aggregate length of calcification is > three vertebra4

#### Cover Story ESC Guidelines & Their Implementation

#### continued from page 11

ischaemic HF and left ventricular systolic dysfunction, until future studies shed more light.

#### Other treatment options

Other pharmacological treatments are recommended in specific situations, i.e., in those with HF and angina nitrates and amlodipine, which can safely relieve anginal symptoms; for atrial fibrillation, amiodarone is the drug of choice and other antiarrhythmics should be avoided; as these patients are at the highest risk of thromboembolism, they should be considered for anticoagulation. Cardioverter-defibrillators and cardiac resynchronisation pacemakers are also recommended in selected HF patients.

Practising physicians ask whether adherence to the guidelines translates into better outcomes in real life. In the MAHLER survey (Medical Management of Chronic Heart Failure in Europe and its Related Costs) the impact of implementation of ESC treatment guidelines on disease outcome was evaluated. This survey, which comprised a population of 1410 HF patients, showed that proper adherence to guidelines is a strong predictor of less HF-related and all cardiovascular hospitalisations in practice. A similar study from Germany concluded that adherence to ESC guidelines was a strong predictor of better survival and the benefit was irrespective of sex, age and left ventricle function.

#### Gap Between HF Guidelines and Clinical Practice

Despite the benefit of adherence to guidelines and European endorsement of them, all reported registries show clinical practice continues to lag behind recommendations. The Euro-Heart Failure Survey II

> was performed between October 2004 and August 2005 in 133 European centres to characterise patients hospitalised with acute HF.

On admission, of those already diagnosed with HF, 63% were receiving ACEi, 38% aldosterone antagonist, but only 46% betablockers and 10% ARB. On discharge, 72% were treated with ACEi, 10% with ARB, 59% with beta-blockers and 54% with aldosterone antagonist. Patients were followed for up to one year and the rate of use of lifesaving therapies in HF was fairly constant (at the end of year: 70%, 15%, 70%, 40% for AECi, ARB, beta-blockers and aldosterone-antagonist, respectively: data not published).

However, the study was performed in experienced hospital centres, and therefore may overestimate the real use of life-saving therapies in non-specialist environments, in which most HF patients are treated. Particularly, it may be the case for combined therapy – though it is estimated, that less than half of HF patients are treated with an optimal combination of ACEi and beta-blockers. Also, as the current use of ACEi and ARB is already fairly high in Europe, the rate of beta-blocker use is still unacceptably low.

#### Arguments Against Guidelines Persist

Many physicians are still reluctant to start beta-blockers in HF patients. Even specialists are using too-low dosages of life-saving medications, as in everyday clinical practice for an elderly, vulnerable patient with many co-morbidities, uptitration of beta-blockers or ACEi may even be dangerous. Other arguments against the application of high doses and combination of life-saving therapies may be that the guidelines never address all the individual aspects such as relative contra-indication, poor tolerance, coexisting co-morbidities, other medications used by a patient, etc., that may impact therapy. However, many studies refute this, as applying a thorough clinical check-up over long-term follow-up together with a rule "start low, go slow" usually minimises side-effects and risks of intolerance and successfully up-titrate a drug dosage.

#### Conclusion

The guidelines have been established to help physicians to treat HF patients in the best, evidence-based way, although there is no doubt that in everyday clinical practice all the rules and recommendations cannot be rigidly applied to every patient. The challenging task of the ESC and the Heart Failure Association is to identify all the potential hurdles and to bring more knowledge, expertise and experience to practicing physicians to further decrease the gap between evidence and practice.



#### Healthcare

### **Economics**



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The application of economics to clinical practice in healthcare does not necessarily mean that less money should be spent, but rather that the use of resources might be more efficient. Broadly speaking, the tools of clinical economics can be applied to the analysis of medical practice to improve decisions on how to allocate resources for clinical interventions.

Here, we will define each type of economic evaluation, highlight the basic similarities and differences, and then focus on the principle components of conducting and reporting a cost-effectiveness analysis, one of the most commonly used economic evaluations used in clinical medicine.

#### Cost-Identification or Cost-Minimisation Analysis

Cost-identification analysis is used to describe and quantify the cost of a particular type of medical care or the economic burden of a disease. This type of analy-

## PRINCIPLE COMPONENTS OF CONDUCTING AND REPORTING A COSTEFFECTIVENESS ANALYSIS

The fundamental principle of economic analysis is that choices have to be made between alternative uses of resources, as there is a finite pool of resources with which to provide all medical care possible to each individual. This principle is not debated. By providing estimates of outcomes and costs, these analyses illustrate the tradeoffs involved in choosing among a variety of clinical interventions to provide the best healthcare. Never before has it been more apparent than in our current healthcare environment that these tradeoffs are inevitable.

sis, also referred to as "cost-minimisation analysis," asks the question, "What is the cost?". An implied assumption is that the health outcomes of different preventive, diagnostic or therapeutic strategies are considered equivalent. E.g., an analysis that assumes the effectiveness of abdominal hysterectomy and laparoscopic-assisted vaginal hysterectomy are equivalent, and that women's preferences for each are equivalent, might simply report the costs associated with each. Although these types of analyses may identify the least costly way of obtaining an appropriate outcome, they cannot specifically predict what the relationship of cost to health outcome will be.

#### Cost-Effectiveness Analysis (CEA)

Cost-effectiveness analysis incorporates information about both costs and health outcomes to describe the value of a particular healthcare programme. CEA eval-

uates an intervention through the use of a cost-effectiveness ratio. In the ratio, all health outcomes (compared with a clearly stated alternative intervention) are included in the denominator, and all costs or changes in resource use (compared to a clearly stated alternative intervention) are included in the numerator.

This type of analysis can be used to compare more intensive forms of an intervention with less intensive forms (e.g., screening every year vs. every three years for cervical cancer); a new technology with the standard of care (e.g., laparoscopy vs. laparotomy); prevention of a problem versus treating it (e.g., behavioural school interventions to reduce rates of sexually transmitted diseases in teens vs. a school-based clinic to provide early treatment of these infections). These types of analyses define the "opportunity cost" of each choice, and provide important data to decision-mak-

ers in diverse settings for making informed decisions about interventions.

The particular type of cost-effectiveness analysis that uses Quality-Adjusted Life Years (QALYs) as the measure of outcome is sometimes referred to as a cost-utility analysis (CUA), although may alternatively be referred to as one type of cost-effectiveness analysis. Cost-utility analysis is a methodological approach to assessing the value of a given health technology programme, or intervention. As such, it can be considered a process innovation designed to inform decisions about utilisation and coverage of medical interventions.

#### Cost-Benefit Analysis

Cost-benefit analysis differs from CEA in that it values both health outcomes and costs of medical interventions in dollars. Because clinical benefit is measured in terms of currency, a net benefit or net cost can be calculated by subtracting the cost from the benefit. The criteria that cost-benefit analysis relies on is whether the benefits of a preventive, diagnostic or therapeutic programme outweigh the costs, the premise being that if clinical programmes that fulfil those criteria are adopted, decisions will be made that will result in an "optimal" solution within the economic welfare framework.

The most common methods of assigning dollar value to health outcomes are willingness to pay and human capital. Willingness to pay, a monetary measurement obtained by estimating an individuals willingness to pay for life-saving or health-improving interventions, can be assessed by a survey that relies on an approach called "contingent valuation", or it can be indirectly inferred from decisions that have actually been made that involve tradeoffs between health and

money. Human capital values health in terms of the productive value of individuals in the economy.

Despite these difficult measurement issues (i.e., the assignment of a dollar value to outcomes like mortality, functional status and quality of life), cost benefit analyses do appear in the clinical literature. Because it requires valuing all outcomes in monetary terms, it allows for comparison to other sectors of society where benefits are not clinical health outcomes (i.e., environment, education, and defence spending).

#### Cost-Effectiveness Ratio

Cost-effectiveness ratio is the measure used to express the results of a cost-effectiveness analysis and represents the incremental price of obtaining a unit health effect (i.e., dollars per year of life saved or per quality-adjusted life year saved) as a result of a given clinical intervention when compared to the next best alternative. In this ratio, two alternatives are being compared with the difference in their costs being divided by the difference in their effectiveness. Cost-effectiveness ratios should be reported as dollar per unit of effectiveness stating the year of the costs, for example, 25,000 dollars per life year saved (1998 dollars).

Cost-effectiveness analyses are always incremental with the ratios comparing each intervention to the next most effective alternative. This means that the costs and clinical benefits associated with the intervention of interest should be compared to existing practice and to all other reasonable options. When all possible alternatives are not included, there is a risk of coming to an incorrect conclusion that an intervention is cost-effective, but only because it was compared with a cost-ineffective alternative.

#### Cost-Effectiveness Analysis and Resource Allocation

A systematic consideration of cost-effectiveness in decisions concerning the implementation of healthcare technologies would contribute to the efficiency of the healthcare system. This goes further than the initial decision to finance a new healthcare technology based on a favourable cost-effectiveness ratio. A systematic approach should raise and solve questions of broader resource allocation. The opportunity costs involved with implementing a new technology should not be restricted to the 'old' substituted technology but to all resources available to the healthcare funder.

An imaging test with highest diagnostic accuracy is not necessarily the test of choice in clinical practice. The decision to order a diagnostic imaging test needs to be justified by its impact on downstream health outcomes. Decision analysis is a powerful tool for evaluating a diagnostic imaging test on the basis of long-term patient outcomes when only intermediate outcomes such as test sensitivity and specificity are known. The basic principles of decision analysis and "expected value" decision-making for diagnostic testing are introduced.

The appearance of more CEAs in the literature in the future will create new insights into the reasons for the high cost of medical care and uncover ways to decrease unnecessary expenditures. Readers of this literature must become familiar with the basic vocabulary, rationale, and standard methods of CEA. By improving our knowledge and understanding of this state-of-the-art research tool, the community will have a greater ability to participate in health-care policy setting and decision-making locally and nationally.





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Historically, like in many other countries, social insurance played an important role in the development of Greek healthcare services. In particular, the Social Insurance Fund (IKA) established in 1937 and the Farmers' Social Insurance Fund (OGA) established in 1961 contributed significantly to the development of the healthcare system.

However, despite early efforts by the government and other parties, the healthcare system in Greece remained one of the least developed amongst OECD countries until the beginning of the 1980s, with many gaps in the delivery, organisation and funding of healthcare. The system was characterised by lack of infrastructure or adequate funding, with great inequalities in access to healthcare.

In this context, the healthcare reforms introduced in 1981 were much needed. At that time, a National Health System (ESY) was established, aiming at providing free, equitable and comprehensive health coverage to the entire population. The 1980s were primarily devoted to the implementation of the reforms and saw significant improvements in the capital, human and technological infrastructure of the public healthcare sector.

## AN OVERVIEW OF THE HEALTHCARE SYSTEM IN GREECE

The Greek healthcare system is characterised by the coexistence of a National Health System (NHS), compulsory social insurance and a strong voluntary private healthcare system. The NHS provides universal coverage to the population and in addition, the entire population is covered by social insurance funds and 15% of the population maintains complementary voluntary health insurance coverage, which, together with out-of-pocket payment, funds a quite large private healthcare market.

In the period between the early 1990s and today, investment in the public sector continued, with greater emphasis placed on managerial and organisational reform to increase the efficiency of the system. An important development in this period was the evolution of the private healthcare sector, which now accounts for more than half of healthcare expenditure. Today, therefore, the healthcare system in Greece is a mixed one where the NHS, public insurance funds and the private sector are all involved significantly in the funding and provision of healthcare services.

#### Organisation

The NHS includes around 130 general and specialised hospitals, totalling about 40,000 beds financed by the state budget and social insurance funds and provide emergency, outpatient and in-patient care. There are also approximately 13 military hospitals and two university hospitals managed and funded by the Ministries of Defence and Education respectively, with a total capacity of about 4,000 beds. The public healthcare system also comprises about 200 Primary Care

Health Centres and 1,500 Rural Medical Surgeries which provide primary care services in rural areas free of charge and are funded by the state budget.

This primary, secondary and tertiary public healthcare system is managed by seven Regional Health Authorities, run by Executive Officers who report to the Ministry of Health and Social Solidarity. The latter has responsibility for developing health policy and coordinating healthcare delivery. The Ministry also supervises bodies such as the National Drug Organisation, the National Emergency Service, the National Centre for Communicable Diseases, and various other specialised institutions.

#### Role of Social Insurance Funds

Around 30 social insurance funds purchase healthcare services for their covered population from the NHS but also from private providers. The majority of the funds are independent entities covering different occupational groups supervised by the Ministry of Labour and Social Affairs. Each provides different benefits and coverage.

#### **Country** Focus

Healthcare Indicators	OECD	GREECE	DIFF
Insurance Coverage			
Public insurance coverage of population	93%	100%	7%
Private insurance coverage of population	28%	16%	-13%
Demographics			
Share of population aged 65 and over	15%	18%	3%
Fertility rates, number of children per women (15 - 49)	1,6	1,3	-0,4
Risk Exposure Indicators			
Alcohol consumption in litres per capita	9,5	9,0	-0,5
Overweight rates, population aged 15 and over	33%	35%	2%
Obesity rates, population aged 15 and over	15%	22%	7%
Percentage of adult population smoking daily	24%	39%	14%
Health Indicators			
Life expectancy at birth	78,6	79,3	0,7
Infant mortality rates	5,4	3,8	-1,6
Suicide mortality rates	12,1	2,6	-9,5
Road accident mortality rates	10,3	16,4	6,1
Low birth weight, percentage of total live births	6,6	8,8	2,2
All cancer, age-standardised mortality rate, per 100,000 people	171	153,7	-17,3
Ischemic heart disease mortality rate, per 100,000 population	102,3	82,9	-19,4
Stroke, age-standardised mortality rate, per 100,000 population	60,45	98,5	38,1
Hospital Infrastructure			
Acute care hospital beds per 1,000 population	3,9	3,8	-0,1
Long-term care hospital beds in hospitals, per 1,000 population aged > 65	5,7	5,0	-0,7
Occupancy rate of acute care hospital beds, in percentage	75%	79%	3%
Average length of hospital stay	6,3	6,0	-0,3
Technology Infrastructure			
Number of CT scanners per million population	20,6	25,8	5,2
Number of MRI units per million population	9,8	13,2	3,4
Number of Mammographs per million population	19,9	36,5	16,6
Human Resources			
Practising nurses per 1,000 population	8,9	3,8	-5,1
Practising physicians per 1,000 population	3,0	4,9	1,9
Growth in practising physician density, 1990 - 2005	1,60%	2,60%	1,0%
Ratio of practising nurses to practising physicians	3,0	0,8	-2,2
Economic Indicators			
GDP per capita, dollars PPP	\$30.149	\$29.578	-571,0
GDP annual growth rate 2000-2005	1,7%	4,0%	2,3%
Healthcare Expenditure Indicators			
Total expenditure on health as % of GDP	9,0%	10,1%	1,1%
Public expenditure on health as % of GDP	6,5%	4,3%	-2,2%
Private expenditure on health as % of GDP	2,5%	5,8%	3,3%
Percentage of public expenditure on health	73%	43%	-30%
Percentage of private expenditure on health	27%	57%	30%
Annual growth rate of total expenditure on health	4,0%	4,7%	0,7%
Healthcare Expenditure			
Total expenditure on health, per capita USD PPP	\$2.759	\$2.981	\$222
Public expenditure on health, per capita USD PPP	\$2.005	\$1.277	-\$728
Private expenditure on health, per capita USD PPP	\$748	\$1.703	\$956
	J, 10	¥1.705	4555

Table 1. Greece vis a vis OECD average in regards to health and healthcare indicators

The IKA covers 50% of the population, the OGA covers 20% of the population, the Fund for Merchants, Manufacturers & Related Occupations (OAEE) covers 13% of the population and the Fund of Civil Servants (OPAD) covers 12% of the

population. Apart from purchasing services, the funds also provide healthcare services through their own centres.

Finally, the private sector, which comprises physicians, practices, diagnostic cen-

tres, laboratories and hospitals has seen significant growth over the past decadeand-a-half and the healthcare system in Greece is moving towards greater privatisation. This trend is influenced by economic growth, the dissatisfaction of the public with access to and quality of public care and the oversupply of doctors and other private services which enhance the demand for healthcare through supplier-induced demand phenomena.

#### Financing and Expenditure

The public healthcare system is financed through a mixed system, in which the salaries of personnel are covered directly by the state budget, while the rest of the expenses are supposed to be covered by service charges to the insurance funds and patients. Charges are calculated on the basis of a complicated reimbursement system, which in some cases accounts only for the duration of hospitalisation, in others for the consumables and medications dispensed and in others on a pre-fixed fee for the intervention undertaken.

In other words, several different reimbursement methods coexist depending on the case. Personnel exclusively employed in the public sector are not allowed to pursue parallel private activity. As the reimbursement fees for the services delivered have not been updated for some time, hospitals and other public services are running huge deficits which are covered by the state budget every few years.

The healthcare budget is set annually by the Ministry of Finance. Taxes account for 70% of the financing of the NHS and the rest comes from social security and out-of-pocket payments. The healthcare services of public sickness funds are directly financed by them and physicians are also allowed to pursue private practice. The private sector is financed through charges to the sickness funds, private insurances and patients themselves. OPAD for instance has contracts with 20,000 doctors and laboratories to cover the healthcare needs of its beneficiaries.

#### Human, Capital and Technological Resources

There are more physicians per capita in Greece than in any other OECD country. During the past decades, the number of doctors per capita increased rapidly to reach 4.9 practising physicians per 1,000

population. It should be also noted that there is a very large number of specialised physicians in comparison to other countries and that only 5% of doctors are general or family practitioners. On the other hand, there are only 3.8 nurses per 1,000 population, much lower than the average of 8.6 in the OECD countries.

In this context the country has the lowest ratio of nurses to physicians among OECD countries. As in most OECD countries, the number of hospital beds per capita in Greece has fallen over time. This reduction has coincided with a reduction of average length-of-stay in hospitals and an increase in the number of surgical procedures performed on a same-day (or ambulatory) basis. The average length of stay is six days and the occupancy rate of hospitals stands at 79%. In conclusion, the healthcare system nowadays has the same infrastructure as in other OECD countries, but it is characterised by an oversupply of doctors and a shortage of nurses, which causes operational and service distortions and supplier-induced demand phenomena.



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The Hellenic Cardiological Society (HCS) was founded in Athens on September 7, 1948, and has been closely linked to the history of cardiology in Greece. The HCS is also one of the 14

## THE HELLENIC CARDIOLOGICAL SOCIETY

Profile, Structure & Goals

founding members of the European Society of Cardiology. The HCS is a scientific, non-profit making association. Initially it had 29 members but the number since has risen to more than 2,000. The vast majority of members are cardiologists, but there is also a small number of cardiothoracic surgeons. The number of Greek women cardiologists is steadily increasing over the last years, and it now represents 15% of the HCS members.

According to the bylaws of the HCS, the aims and targets of the society are the promotion of the discipline of cardiology in Greece, the participation in the prevention and treatment of cardiovascular diseases and the achievement of the best possible scientific and professional conditions for the members of the HCS.

The HCS is managed by the Board consisting of nine members namely, the President, President-Elect, Past-President, Secretary, Treasurer, and four Members. The Board Members are elected through elections (secret-balloting process) that take place every two years, during the procedures of the Annual Panhellenic Cardiological Congress. In these elec-

tions, all members of the HCS are eligible to participate and vote. The President of the Board is the President-Elect of the previous Board.

The HCS comprises 19 working groups. Each of these working groups has as its subject a specialised scientific area of cardiology and is managed by its President, President-Elect and the Nucleus Members. The members of each working group meet regularly, organise educational and research activities, registries, and publish guidelines.

The HCS owns a five-story building of great architectural value, the "Heart House", in which the administrative services and several of the scientific and educational activities of the society are hosted.

The HCS organises a three-day Annual Panhellenic Cardiological Congress, held in October or November each year, that focuses on high-quality round table talks and lectures given by distinguished Greek and invited foreign speakers, as well as the presentation of abstracts with original research. The congress is the largest medical congress in Greece and is attended by more than 2,500 cardiologists, physicians from other specialties and nurses.

Additionally, the Annual Seminar of the Working Groups of the HCS, held in February or March each year, provides a more focused exchange of scientific knowledge, based on the specific subject of each working group. This annual seminar is mainly characterised by round table talks and lectures, with very limited presentation of abstracts of original research.

In addition to the above, the HCS has been organising activities, actions and events, taking place throughout the year and all over Greece, characterised by a high scientific level.

The HCS also publishes the Hellenic Journal of Cardiology, its official bimonthly scientific journal, indexed in the Index Medicus. In addition, the newsletter of the HCS, containing information on past and future activities of the society, is published every three months and is mailed to all members.

Of primary importance is the website of the HCS (www.hcs.gr). The home page of the HCS contains information on the HCS, the working groups, the full-text content of the Hellenic Journal of Cardiology, the upcoming meetings, and the electronic library, through which all the members of the society have full-text access to the most important international cardiological and other scientific journals.

Several other activities are fostered by the HCS, aiming at the improvement of education and motivation of gifted cardiologists. The society sponsors grants, awards and scholarships. Grants are given for original research projects submitted according to pre-specified rules. The awards are given during the Annual Panhellenic Cardiological Congress for original abstracts presented during the Congress. The scholarships are destined for young cardiologists, under the age of 40 years, who wish to follow specialised training for one year in prestigious centres of cardiology abroad (most often in Europe, but some times in the US).

As the years pass, the HCS becomes more and more open and democratic and includes younger cardiologists in the educational programmes and as speakers in its scientific meetings. In addition, all Greek cardiologists are encouraged to submit their original research abstracts to the Annual Panhellenic Cardiological Congress and submit their papers for publication to the Hellenic Journal of Cardiology.

#### Strong Ties With the ESC

The HCS is closely related to the European Society of Cardiology (ESC). One could say the ESC acts as a guide for the HCS. The HCS may adopt several of the ideas and activities of the ESC; however, it should be stressed that such ideas and actions are actively adjusted to the unique conditions of the Greek cardiologists. Cooperation between the ESC and the HCS is always welcomed and communication channels between these two organisations are always wide open.

The HCS constantly seeks new ways and means for the advancement of cardiology in Greece, therefore always seeks the development of new activities that will fulfill its goals and aspirations. To achieve this, the society engages in activities aiming to reach the general public, such as brief television messages against smoking and obesity and promoting healthy eating and exercise. The HCS participates in activities for educating the general public during the World Heart Day each year and makes clear, simple statements about controlling risk factors for cardiovascular diseases.

#### **Future Goals**

Of the most important future goals of the HCS should be the commitment to promote growth of knowledge about cardiovascular diseases and improve disease prevention by providing information to cardiologists and to the general population. Another important goal should be the assumption of a strong advisory role by the society for the development of standards for training and credentialing of young cardiologists.



AUTHOR

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In Greece, as in most European countries, four years of cardiological training follow two years of training in internal medicine. The training programme during the four years in cardiology follows the requirements of the Chapter on Training of Medical Specialists in the European Union and has been endorsed since 1990 by the Hellenic Society of Cardiology. Thus the training time is allocated as outlined in Table 1 (see below).

It should be noted that the number of trainees per programme corresponds roughly to one resident/fellow per four department beds. This may not be practical for many departments, which for the same number of patient beds have more active laboratories and intensive care units. Accordingly, modifications to address these issues are currently being implemented.

Rotation	Months
Ward duties	18
Coronary care unit	3
Echocardiography laboratory	6
Electrophysiology laboratory	3
Haemodynamic laboratory	9
Exercise electrocardiography,	3
Nuclear laboratory	
Paediatric cardiology - Cardiac surgery	3
Elective rotation	3
TOTAL	48

Table 1. Division of Training Time in Months

## EDUCATION OF CARDIOLOGISTS IN GREECE

#### An Overview of the System

Cardiovascular diseases, as the primary cause of mortality and morbidity, have increasingly necessitated the expansion and development of new methods of cardiovascular care. Moreover, practical skills have evolved dramatically in three new areas; echocardiography, electrophysiology and interventional cardiology. Thus, the modern cardiologist is faced with a great expanse of theoretical knowledge in which he has to become an expert.

Under the conditions described and again according to the European specifications, every trainee by the time of completion of his training should have acquired experience by performing and interpreting the examinations or procedures outlined in Table 2 (see below).

The trainee should participate in the study, review, and discussion of all these procedures although not all hospitals can afford these facilities.

According to a survey conducted in 2003 by Dr. Evangelos Papasteriadis, former President of the Hellenic Cardiological Society: "Approximately 92 hospitals in Greece provide at least one year of accredited cardiology training, while 41 offer full training. Among those, not all offer full haemodynamic and or electrophysiological laboratory facilities. Residents training in these hospitals rotate in other departments to complement their training".

Ideally, fellows should keep log-books in which they record their participation in various procedures and the grading through their rotations.

#### Trainee Log-Book from Onassis Cardiac Surgery Centre

The log-book system has been implemented in our centre since 1993, in

which the following activities are recorded over four years.

#### Education

- Previous training centres;
- In-hospital education such as lessons/seminars/presentations (60% attendance compulsory), and
- Extramural education such as courses, seminars, congresses, etc.

#### Four-year Training Activities

- Wards;
- Outpatient clinics;
- Coronary care unit;
- Echocardiography laboratory studies recorded;

Non-invasive procedures	No. of hours
Simple electrocardiograms	1000
Holter electrocardiograms	200
Exercise electrocardiograms	300
Echocardiograms	500
Pacemaker programming	50
Nuclear studies	50
- participation: 40	
- sole operator: 10	
Invasive procedures	
Temporary pacemaker insertion	10
Swan-Ganz	20
Right and left heart catheterisation	25
Coronary arteriography (participati	on) 300
PCI (participation)	50
Interventional electrophysiology	25

Table 2: Areas of Trainee Participation and Relevant Hours Spent on Each Area

- Haemodynamic laboratory interventions recorded;
- Electrophysiology laboratory interventions recorded;
- Exercise, and
- Nuclear laboratories.

#### **Scientific Activities**

- Presentations and attendance levels at in-hospital courses, seminars and congresses;
- Publications in Hellenic and international scientific journals, and
- Participation in multicentre trials.

One very important aspect of the training programme is teaching/education. According to the American Board of Internal Medicine, trainees should participate in teaching activities for at least 4.5 hours per week. These activities should include teaching rounds, lessons and seminars. The curriculum followed usually corresponds to the Core Curriculum for the General Cardiologist prepared by the Education Committee of the European Society of Cardiology in 2003.

Also, the US Accreditation Council for Graduate Medical Education (ACGME) has offered the following specifications for the teaching faculty of hospitals of accredited training and teaching hospitals. There should be at least four instructors in programmes with more than six trainees. They should devote 20 hours per week to teaching, research, administration and resident evaluation.

#### Additional Training Activities

Apart from the training provided by each individual hospital, efforts have been made to offer formal teaching courses in the form of the 'Board Review Course' as modeled by the US, to a number of trainees. Our department thus instituted two three-day seminars per year from 1997 until 2003 and the Hellenic Cardiological Society instituted a year long series of courses since 2003, during the presidency of Prof. Harisios Boudoulas. These courses have proven very successful.

#### **Evaluation of Trainees**

Each individual hospital offers various ways of evaluating their trainees. Most consist of written examinations every six or 12 months.

At the completion of their training, all residents/fellows have to pass state examinations to become licensed as practicing cardiologists. These examinations have evolved over many years. In their current form in the Athens/Piraeus area, the format is that introduced by the author as Chairman of the State Examination Committee in the years 2004 and 2005.

#### First day

- Written examinations;
- 10 questions requiring detailed review and discussion;
- 20 multiple choice questions, and
- 10 spot-diagnostic tests, including ECGs, echocardiograms, cineangiograms, etc.

The fellows proving successful in the written examinations proceed to the clinical patient case-examinations.

#### Second day

programmes.

Each candidate is assigned to study one patient for about two hours and then is examined by the committee, which consists of a Senior Professor of Cardiology in the University of Athens and two Department of Cardiology Directors from Hospital in the Athens/Piraeus vicinity.

Here some problems and weaknesses of the cardiology training programmes in Greece should be reviewed:

a. The main problem is the long waiting time to enter an accredited training programme, which can stretch to up to seven years. Thus, many candidates have to do with their second or third choice programmes or go abroad to start training. b. The lack of homogeneity among programmes, some being of much higher quality than others. As already stated, not all hospitals offer full training

An effort has been made over the last few years to remedy these problems by the following approaches:

i. To offer to smaller or district hospitals the opportunity to form associations with larger hospitals; thus the residents can carry out their clinical training in the first group of hospitals and continue their training in the second.

ii. By modifying the one resident/4 patient bed ratio for hospitals offering a very large range of interventions, both haemodynamic and in electrophysiology.

#### Continuing medical education

This aspect has not been as formally organised in Greece as hospital training. The one formal state-accredited sub-specialty training is in echocardiography, where approved hospitals offer six months of training, after which the trainee undergoes state examinations to become certified in echocardiography.

There have been many efforts to recognise interventional cardiology as a one-year subspecialty training, but this has not been approved anywhere in Europe. However, many hospitals offer training in this subspecialty, as well as in invasive electrophysiology. This type of training is unofficially recognised as an asset, mostly in private hospitals.

There is no formal recognised training course leading to a diploma for the private, practicing cardiologist. However, most meetings, seminars, and congresses offer points for continuing education, through a state-Hellenic point system, the European EBAC and the American Continuing Medical Education (CME) systems.

Altogether, cardiology is one of the medical specialties in Greece which offers a training programme of quite satisfactory quality.

Every effort should be made to improve standards, both as regards hospital training but especially so in the field of continuing education.

## Cardiology **Leaders**



**Prof. C. Stefanadis**Dean of the Medical School
University of Athens

INTERVIEWEE

University of Athens Chairman First Department of Cardiology University of Athens Athens, Greece

#### Please tell us about your background in the field of cardiology.

I graduated from the University of Athens Medical School in 1971 and during my undergraduate studies, I had the chance to attend subspecialty rotations, during which I was captivated by exciting advances in the field of cardiology. I was particularly inspired by the development of invasive cardiology. It was my belief that cardiology would give me the opportunity to develop as a clinician and as a researcher. Therefore, my choice to follow a career in the field of cardiovascular diseases came as a natural consequence. My post-graduate training was obtained in the department of cardiology of Athens University at Hippokration hospital, under the directorship of Prof. Avgoustakis. I received my PhD in 1988 after which, I pursued a research fellowship in the department of cardiology at Ohio State University, US, on the elastic properties of the aorta.

### What are your specific areas of interest within this field and how has this evolved?

My heart belongs to interventional cardiology. Our hospital, was the first hospital in Greece in which percutaneous angioplasties were performed. A novel era was beginning and I had the chance to be part of it. I focused on developing my skills and expanding my knowledge. Aside from my clinical work, I was involved in numerous research protocols designed several catheters that were applied both in the experimental setting and in patients with cardiac disease. In 1983, I joined the permanent staff of the First Department of Cardiology in Athens Medical School and a few years later I was appointed chief of the coronary care unit and the cath lab. In 2002 I became professor of cardiology and in 2003 I was appointed Head of the First Department of Cardiology in Athens Medical School. In 2003 I was elected Vice-Dean and in 2007, Dean of the Athens Medical School.

#### Please tell us a little about your current professional position.

The First Department of Cardiology at the Athens Medical School has 40 beds in the various wards and 14 beds in the coronary care unit. It has an echocardiography laboratory, a non-invasive laboratory that offers exercise and pharmacologic stress testing, three catheterisation laboratories that offer a comprehensive approach to the treatment of coronary artery disease, structural heart disease, arrhythmias and congestive heart failure and a biochemistry lab. Furthermore, there is a cardiology outpatient clinic, a hypertension clinic, a lipid clinic, a heart failure clinic, an adult congenital heart and pulmonary hypertension clinic, as well as a peripheral vessels clinic.

### What are the main management challenges you face in your working life?

The greatest challenge is to keep up with the growing demands for optimal health provision in an era of steadily increasing financial pressure. Furthermore, these demands need to be met effectively and certainly not at the expense of research, which is a fundamental component of a university setting.

### What is your advice for improving teamwork and generating good staff morale within your team?

It is very important to acknowledge the work and expertise of every staff member. Every colleague's clinical and research programme should be encouraged. Furthermore, it is essential to distribute responsibilities fairly and to encourage initiative-taking and leadership.

#### How does your department ensure medical safety and what guidelines do you follow?

We practice clinical cardiology in compliance with national and European guidelines. In order to ensure medical safety, we keep full records of every patient admitted to our department or seen in an outpatient setting. All information is entered into our database and our statisperiodically reviewed. tics are Furthermore, we consistently perform morbidity and mortality rounds and discuss the most challenging cases. In addition, doctors, nurses and technicians are encouraged to participate in congresses and at meetings in order to expand their knowledge.

#### What sorts of modern technology does your department use?

Each department has cutting-edge techcontinued on page 25

#### Biotechnology and Cardiovascular Medicine

#### **IHE INTEGRATION PROFILES**

Optimising Cardiology IT Interfacing

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In the past, communication or data exchange between all these systems was impossible. For example, it was necessary to enter the patient name several times into different computer systems. Results from haemodynamic systems or laboratory results had to be re-entered into the CIS. Corrections of errors in patient names were not carried through to the CIS or PACS, a system flaw that doubles work and is a proven source for mistakes.

Interfacing all these systems at a high level is very time-consuming and requires a large effort from vendors and hospital IT administrators. Most of the abovementioned systems are developed by different vendors and operated by different applications in a hospital. That is why in many institutions, these interfaces are not being optimised.

#### Challenges of Interface Development

Usually, interfaces between two systems take into account only whatever data exchange is necessary for those two systems. In real life, all systems work togeth-

Computer applications are indispensable tools in cardiology today for digital image acquisition, deployment and reviewing, and also for documentation, dose reporting, quality assurance and exam scheduling in the Cardiology Information System (CIS). Image archiving systems (PACS) and electronic patient records reduce the required amount of time to access relevant patient information. Furthermore, billing in hospitals is unimaginable without the digital aid of Hospital Information Systems (HIS).

er in a larger environment and interfaces need to follow the requirements of a complex workflow.

The goal of most communication standards like HL7 and DICOM is to exchange information between two parties using flexible configurations. These standards offer a lot of optional fields for additional information - data that might or might not be delivered by a given system. In practice, a receiving system will often not get any information that is required for the next work step. For example, an acquisition modality might send a set of data of a stress echo examination. The receiving system is able to display all images but does not get any useful information about stress stages and views. Without this information it is not able to perform a proper quad screen display. IHE targets exactly this problem. It defines abstract process models of real world workflows and datasets that are required for these workflows.

#### Setting Appropriate Communication Standards

In order to reach this goal, clinical experts and software engineers together define abstract workflow models for given scenarios. Using these abstract models, for each data exchange step between two systems the appropriate communication standard and transmission service is selected. In a final step the required data attributes are selected and specified. At this point IHE might overrule a given standard and define additional attributes that are required. Doing that, IHE reduces ambiguity and potential misinterpretation of present standards.

#### IHE Cardiology Domain

The IHE Cardiology domain was sponsored for the first four years by the American College of Cardiology (ACC) and supported by the European Society of Cardiology (ESC). Representatives from both societies are actively involved

in the work of the IHE Cardiology Committee.

As in other IHE domains - such as Radiology, IT infrastructure or Laboratory - in Cardiology there is a Planning and a Technical Committee. Once a year, the Planning Committee defines the most urgent user demands. In the following months, the Technical Committee reviews existing standards and prepares solutions for the given topics. Every group of topics is handled in a so-called Integration Profile. The technical descriptions of these Integration Profiles are summarised in a Technical Framework. After a public comment phase, the vendors implement the framework into their products. Any problems with the framework are communicated back to the technical committee.

For cardiology there are already several Integration Profiles available. The most important Integration Profiles shall be presented here. A complete set of Integration Profiles is available at www.ihe.net.

#### Primary Cardiology Integration Profiles

Cardiac Catheterisation Workflow: The common workflow in a cardiac cath lab includes patient admission in the HIS, exam ordering and scheduling. Image archiving and notification of the HIS about the performed procedure and the availability of image data is also part of this workflow. Typical for cardiology routine, is the high rate of unscheduled emergency cases. It is not uncommon to

start the exam with the creation of some images and report back all information to the HIS. This scenario is quite a challenge for proper reporting and billing because it is necessary to reference all exam information to the 'official' patient data set handled by the HIS.

Echocardiography Workflow: This workflow is very similar to the cardiac cath workflow as described above. Although ultrasound exams are commonly not performed in emergency situations, another characteristic is relevant from the IT point of view. Ultrasound systems are generally mobile units and therefore not always connected to a wired computer network. This results in problems in exam scheduling for this area. These problems can be covered using this Integration Profile. Another goal of this profile is the proper indication of stress stages and views for stress echo exams. These data can be used by a viewing station for a proper simultaneous display of different stages or views in a quad screen.

Retrieve ECG for Display: A typical problem in cardiology is the quick and easy distribution of ECGs inside or outside of the cardiology department. This Integration Profile makes use of web technology to distribute ECGs in PDF format. This feature might be used stand-alone in a web browser or as an embedded function of an electronic health record.

Displayable Reports: Reports in cardiology not only contain plain text and numbers. Very often they also contain images,

graphics or tables. For a safe layout control this Integration Profile uses the PDF format to create reports. These reports can be sent from image analysis workstation to the PACS or HIS so they are available very quickly and can be sent to the EMR without producing paper printouts.

Implantable Device Cardiac Observations: A new and promising Integration Profile, this handles the topic of implantable devices – such as pacemakers or defibrillators that need to be verified in regular terms using vendor proprietary equipment. Until now, these data can be collected in vendor databases only or sent to a paper printer. Using this profile the data from devices of different vendors can be sent over a network – which also might be a wide area network – and collected in one and the same database for further analysis or long term storage.

#### Validating Integration Profiles

All the above-mentioned Integration Profiles were validated in a practical setting during "Connectathons", events where engineers from different vendors come together and exchange information following the specifications in the Technical Frameworks. IHE offers several advantages for the clinical user. IHE compliant products have already proved their ability to exchange data following the IHE specifications defined in the Technical Framework which includes detailed descriptions of the expected behaviour of each involved system. Therefore these documents can be used by hospitals for describing their demands on new systems and their interfaces.

#### continued from p.23

nology and equipment. The cath lab is equipped with the latest technology with a variety of diagnostic devices available, such as intravascular ultrasound devices, OCT and thermography devices. Besides routine PCIs, a wide range of interventional procedures such as valvuloplasties and atrial septal defect closures are carried out using the latest medical tech-

nology such as intracardiac ultrasound. Certainly, with such devices our department has the possibility to tailor the management of each patient according to his or her needs.

Finally, what three key rules are essential to other cardiology managers & administrators?

The following should be considered essential:

- (a) Compliance with established guidelines:
- (b) Monitoring and discussion of adverse events, and
- (c) Encouragement of research in compliance with national and international standards.

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For many years, there have been remote transtelephonic systems to assess pacemaker battery life, but the new generation of remote monitoring systems are more powerful, both in terms of diagnostic information from the device and information about the patient's disease process. Current systems can provide the same information that can be obtained in an in office visit, with the exception of pacing thresholds.

#### Why Use Remote Monitoring Systems?

Remote monitoring has numerous benefits. First, patients will not have to be seen in the office as frequently, in some cases, saving 3 - 4 trips to the physician per year. This increases patient satisfaction, time savings, cost savings to the patient and easier follow-up. This is particularly useful for patients that travel extensively in the US and for "snowbirds" who reside away from their primary residence for part of the year, yet want continuity of care with their primary device clinic.

#### REMOTE **MONITORING ADOPTION**

One Clinic's Experience

Over the past 12 months, there has been a rapid and widespread introduction of remote monitoring systems by most manufacturers of implantable cardiac devices. While there are differences in these systems, the underlying premise and benefits to patients and healthcare providers are similar.

Despite these advantages, some patient barriers do exist. Patients worry they will lose contact with their physician with fewer face-to-face visits. These fears are easily addressed by the fact that the patient will still have as much or more contact with the physician over the phone, and more frequent interrogations when needed. With the recent device company recalls and advisories, remote monitoring is a way for clinicians to follow patients closely and offer security to patients that are fearful of the implications of these advisories on their health.

#### Remote Monitoring Addresses Capacity Concerns for Clinics

A second beneficiary of remote monitoring is the clinician and Arrhythmia Device Clinic. With the rapid increase in device implantation, many clinics are dealing with capacity concerns. Remote monitoring will decrease the frequency of in-office visits over time, freeing up the staff to perform other duties. By converting patients to remote monitoring, a clinic can take advantage of batch processing. One can schedule all the remote monitoring patient follow-ups to occur on a particular day or days, thus making clinic staffing more predictable.

For example, in our clinic, we have designated two days of the week for remote monitoring. Thus, we can download a large volume of data at these times, and

provide analysis at some time thereafter. By allowing for controlled use of one's time, planning a day's activities can be made easier. Nurses that perform other duties (EP lab, etc.) can perform those duties and remote monitoring tasks at other times of the day, in between cases, early in the day, or when downtime occurs. Additionally, remote monitoring can reduce the number of emergency department visits for both appropriate and inappropriate device therapies, with both physician and nurse being able to evaluate the therapy from their office or home.

#### Increasing Clinic Coverage

This efficiency also applies to the physician managing a busy device clinic. Balancing the need to do cases and provide coverage for a clinic can be a daunting task. With remote monitoring and fewer in-office visits, a physician can devote more time to other tasks, and yet still monitor patients closely by overreading remote monitoring interrogations later in the day or during downtime. Over time, the adoption of remote monitoring will decrease office visits, increase remote monitoring visits and increase nurse and physician efficiency.

Finally, remote monitoring opens a new frontier of disease management and database analysis. With advances in sensor technologies and heart rate data, informa-

continued on page 28

### 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 subject 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 softer 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 suffer 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.

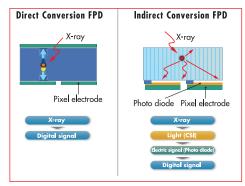


Fig. 1. X-ray Conversion Method for Moving Image FPD

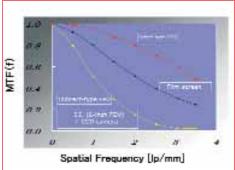


Fig. 2. Comparison of MTF Curve for Different X-ray Detectors

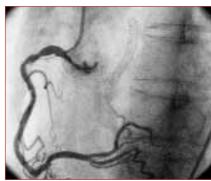


Fig. 3. Right Coronary Artery/Shimadzu Cardiac/Angiographic System

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tion is available that can help manage disease processes such as congestive heart failure or even predict decompensation. This helps prevent hospitalisations or clinical events. In database management, data accumulated by remote monitoring can be queried for early signs of issues with leads or devices.

#### Our Clinic's Experience with Remote Monitoring Adoption

Our clinic began using Guidant's LATI-TUDE remote monitoring system in the spring of 2006 and the Medtronic Carelink system in the spring of 2007. We currently have over 350 patients in these systems. As a busy urban tertiary care academic centre, our device clinic volume has seen dramatic increases. In addition, our nursing staff are cross trained and run both the device clinic as well as our busy inpatient electrophysiology laboratory. Thus, as our volume of implants increased, driving up our device clinic visits, our staff was affected both on the inpatient and outpatient side. Device clinic follow-up days were full and often double-booked. In addition, wait times for visits were increasing.

As with any new technology, there was a learning curve for remote monitoring. Initially, there were issues regarding technology, patient enrolment, patient interrogations and downloading data. There were frustrations with the technology that soon yielded to the increased efficiencies that the technology promised. Using two dedicated days for remote monitoring, slowly the number of inoffice visits decreased. Given the large volume of our clinic, it may be some time before every patient is on remote monitoring, but the benefits grow with each passing month. We have seen a decrease in wait times for the clinic and less double booking of clinic days.

We have already seen several examples of successes of remote monitoring. These have included numerous evaluations of patients with appropriate ICD discharges that could be reassured that their device functioned properly. Several others have had "phantom shocks", which allowed our staff to reassure the patient that their device had not discharged. Patients who were started on antiarrhythmic medications have been followed remotely to assess response to medications.

We have also avoided re-operation and repositioning of leads by remotely intensifying follow-up, of patients who had early post-operative changes in sensing.

The objectives of the study are to develop and test algorithm-based early detection of heart failure events and to develop and test an index of heart failure risk. This will be achieved by acquiring data from the LATITUDE system of remote monitoring by Guidant. Information collected included: activity logs, heart rate variability, programmed parameter values, arrhythmia logbook, therapy history, histograms, paced/sensed counters and lead impedances. In addition, patients will answer a heart failure questionnaire, record their daily weights and be contact-

### "The adoption of remote monitoring will decrease office visits and increase nurse and physician efficiency"

Finally, trending of lead and battery data have identified battery depletions, lead dislodgements, left ventricular lead issues, silent atrial arrhythmias and lead fractures. These are examples of issues that were identified before a clinical event or an office visit.

#### **DECODE Trial**

As part of our desire to adopt remote monitoring in a multidisciplinary manner, we were eager to be involved in the DECODE (DECOmpensation Detection Study) trial, sponsored by Guidant Corporation (now Boston Scientific). We recognised that even though there is tremendous power in device management with remote monitoring, the true holy grail is disease management. Can remote monitoring alter the outcomes of congestive heart failure in patients implanted with a cardiac resynchronisation therapy (CRT) device?

ed periodically to document heart failure clinical events.

#### Conclusion

Remote monitoring has reached mainstream practice for many reasons. It offers patients the security of closer device follow up and more convenience without sacrificing thorough physician involvement. Remote monitoring promises to make device clinics and physicians more efficient while continuing to provide high quality and thoughtful care to their patients. This will allow the clinic to run more smoothly, offer better time management of staff and physicians and provide more timely evaluation of patients with shocks or potential device malfunctions. Finally, remote monitoring promises to open a door into the future with disease management tools that will hopefully prevent hospitalisations and improve patient outcomes.



## Free Subscription Form



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#### 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)

- 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?

for Cardiology Management

- ☐ More than 30 beds
- ☐ 15 30 beds
- ☐ Less than 15 beds
- 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

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## CARDIOLOGY MANAGEMENT

#### PACS IN THE CARDIOLOGY DEPARTMENT

Report on Market Developments

AUTHOR

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Cardiology Second-Largest PACS Revenue Source

The cardiology department is the largest producer of images, clinical and administrative information and data, which makes it the greatest PACS revenue source outside of radiology. These results essentially rolled out to the creation of dedicated cardiology PACS systems and solutions that include PACS hardware, workstations, archiving in either VHS/DVD storage, or the more advanced SAN application with networking. Some of the other features of these systems are post-processing, analytical tools, clinical reporting, administrative modules for scheduling, patient/material management, billing, and order management.

While there are similarities between a radiology and cardiology PACS, there are also significant differences. The similarities originate in an overlap in the support requirements and infrastructure of the two PACS. In fact, the potential to share core infrastructure such as networking, archiving, digital Managing cross-departmental communications in a healthcare setting has been greatly improved by the emergence of picture archiving and communications systems (PACS) as a vital supporting infrastructure, with specialists in healthcare departments like orthopaedics, neurology, oncology, histology and cardiology improving their communication and therefore patient wellbeing. The integration of all clinical specialties' images within an enterprise-wide PACS will take some more time in a majority of European and APAC practices in order to catch up to an already growing US market, issues which we will explore further here.

imaging and communications in medicine (DICOM) standardisation and, to a lesser extent, front-end equipment such as workstations and modality interfaces, has considerably facilitated the adoption of cardiology modules by PACS-literate hospitals. But with the improvement in the technology, a distinction is also emerging in cardiology between the levels of sophistication of workstations with diagnostic clinicians enjoying higher resolution displays and using more exhaustive software options, encompassed within more powerful workstations.

#### Challenges in Handling Cardiology Data

The other advantage with cardiology PACS is that it can share storage area networks (SAN), which helps in routing through other networks for viewing by cardiovascular surgeons or referring physicians over the hospital's web browser. This integration is certainly a challenge in such a complex and interoperability-dependent environment. The dynamic nature of cardiac images makes it difficult to have sufficient bandwidth to handle cardiology data. Cardiology has unique requirements; these needs come in the form of capturing sound, certain cardiac measurements, and structured cardiac catheter laboratory (cath-lab) and echocardiography laboratory reporting. Cath-lab and echo are the chief modalities that are connected to a cardiology PACS.

Outside of these two main modalities, cardiac magnetic resonance imaging (MRI) and cardiac computer tomography (CT) are gaining rapid popularity from a low base. Cardiology PACS uses

information produced by these modalities, by performing intermediate and final reporting, with capabilities for dealing with blood level and haemodynamic data, as well as analytical tools for measuring stenosis. On the administrative side, cardiology PACS handles disparate tasks like order management, patient and materials management, and scheduling. These functionalities can be accomplished by integration of cardiology information system (CIS), which brings autonomy in the hospital set-up and increases mobility of cardiologists.

This is the reason why 99% of cardiology PACS sales are accompanied by CIS sales. These systems offer workstations that can link these disparate modalities in a single location. The technical conundrum of linking all these demands in one box, and making that box function intuitively, is exacerbated by the fact that cardiology workflow is completely heterogeneous.

#### Cardiology PACS Market Affected by Economic Factors

The market for cardiology PACS is affected by both micro- and macro-economic factors. Technology is expected to exert a great influence on the state of this market, as the level of investment needed by end users to acquire cardiology PACS decreases, while the number options opens to them increases. Advances in connectivity standardisation form the bedrock of this technological progression, as these available solutions will continue to be problematic to interface.

Some of the factors helping market growth for cardiology PACS are the high incidence of cardiovascular disease, which encourages the need for better management of cardiac examinations and information, and the increasing benefits of PACS, which encourages hospital investments in IT solutions for

cardiology. The other factors driving the market is the increase in adoption rates of DICOM with development of cardiology-specific tools.

#### Pricing and Implementation Times a Negative Factor

These associated emerging advantages help enterprise-wide PACS to grow and for these procedures is increasing due to increasing cardiac examination requirements. The cardiology PACS market in the US is around three years behind radiology PACS, but in Europe there is a gap of nearly a decade. However, the number of single lab installations in Europe is higher when compared to the US market. The US market prefers

## "The integration of a cardiology information system increases the mobility of cardiologists"

bring greater workflow efficiency. The issues that impact market growth negatively at the moment are pricing factors and implementation times. In a typical situation, the cost of cardiology PACS installations goes up due to certain mandates like revamp of existing legacy systems, infrastructural costs and the reliability of the vendors, given the large outlay of capital involved. This increases the decision-making time and delays sales of these systems. Financing and leasing options, training and ongoing support services represent other key factors that the end-user seeks in the package.

#### US Market More Advanced than Europe

There is a vast difference between the rate of cardiology PACS adoption in the US and Europe. The US market is much more advanced, as the demand

engaging in multi-lab installations and enterprise PACS as advanced storage solutions, IT architecture, and multi-modality integration helps in a holistic integration of the hospital's IT systems. The pricing difference between these variants also makes a lot of difference. The complete enterprise can easily cost from 550,000 – 650,000 dollars.

More and more end-users in the European market are becoming convinced by the increasing advantages of having a fully-fledged and comprehensive solution for cardiology as well as at an enterprise level for better long-term costs and profitability. The cardiology PACS market in future will be more integrated into the EMR and this trend is causing a growing demand by cardiologists to be able to make notations directly to the patient's EMR.



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MCS was initially designed to support circulation where patients were either heart transplantation candidates or were likely to become candidates after a period of support. The latter category had initially one or more contraindications to heart transplantation usually due to inadequate cardiac output, and it was likely that, after a period of support, the end organ function would recover and they would become heart transplant candidates. The results for this type of indication have been excellent and, although data from multicentre randomised controlled trials are missing, it seems that the previously supported recipients of MCS were having as good as and often better outcomes than the unsupported ones.

#### Bridge to Transplantation (BTT)

The industry developed these devices to support patients up to two years. Left ventricular assist devices (LVADs) like the HeartMate (Thoratec Corp., Pleasanton, CA), Thoratec (Thoratec Corp., Pleasanton, CA), and Novacor (WorldHeart, Oakland, CA) have found widespread worldwide use among transplant centres. Heart failure, in the region of millions both in Europe and the US, is expected to increase due to the ageing population and improved

## MECHANICAL CIRCULATORY SUPPORT

New Generation Devices Mark a New Era

Long-term Mechanical Circulatory Support (MCS) was initially used in clinical practice to bridge patients in end-stage heart failure through to heart transplantation. Rapid developments have, however, led to the use of newer generation devices that promise to minimise the morbidity and mortality associated with their use and to improve the quality of life of patients. This article uncovers the expanding role of these devices and explores their further use.

post-infarction survival rates. Also, the number of heart transplants decreases worldwide due to shortage of donors. For these reasons, it is clear that the future of MCS should lie in the treatment of end-stage heart failure in the general population beyond just transplant lists.

#### Trials Back MCS Therapy

The initial intent for the MCS was destination therapy, an implant that chronically supports the heart failure recipient until death. The discovery of immunosuppressive agents resulted in successful transplant programmes that put this on the backburner until the 90's, when the National Heart, Lung, and Blood Institute (NHLBI) of the US began funding a multi-centre randomised controlled trial (RCT) called Randomised Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial (Rose et al. 1999, Rose et al. 2001).

To date, the REMATCH trial is the only RCT to examine the role of MCS as a destination therapy in ineligible-

for-transplantation end-stage heart failure patients. It compared long-term MCS to Optimal Medical Therapy (OMT) and it employed a pulsatile pump (HeartMate I, a first generation implantable device). It demonstrated a clinically significant survival benefit (52% in the LVAD group vs. 25% in OMT group in one year, p=0.002, and 23% vs. 8% respectively in two years, p=0.09) and an improved quality of life in LVAD-treated patients.

After completion of the REMATCH trial in 2001, MCS for destination therapy was recommended for patients with advanced chronic heart failure (ACHF) not responsive to optimal medical treatment (OMT) and ineligible for heart transplantation.

Another prospective, nonrandomised trial called INTrEPID (Rogers et al. 2007) followed the REMATCH trial and confirmed its results. The INTrEPID demonstrated significant 6-and 12-month survival benefits (survival 46% in the LVAD group vs. 22% in the OMT group, p = 0.03 and 27%

vs. 11%, p = 0.02, at 6 months and 12 months respectively) and improved quality of life in LVAD treated patients who were non-transplant candidates.

#### Old LVADs Inappropriate for Long-Term Support

Despite the fact that the annual candidacy for MCS as destination therapy in the US is estimated to be up to hundreds of thousands of patients per year, fewer than 300 patients were implanted between 2004 - 2006 (Parides et al. 2006).

The Thoratec HeartMate XVE LVAD, known as HeartMate I, used in the REMATCH trial, and the Novacor LVAD used in the INTrEPID trial were the most widely-used first-generation LVADs. The use of these devices in those two trials was associated with several severe adverse events: mainly thromboembolic and neurologic events, infection, bleeding, and device malfunction or failure. In the REMATCH trial, freedom from device replacement at one and two years was 87% and 37%, respectively, and, after sepsis, device failure was the most common cause of death.

It became apparent that the devices built with the BTT indication in mind were not appropriate devices for longterm, permanent support or destination treatment. The need for a new generation of improved devices to address adverse events associated with long-term MCS was evident.

#### Second and Third Generation Devices

In contrast to the first generation pulsatile devices, newer generation devices produce continuous flow. These devices have a simplified pumping mechanism without the requirement for compliance chambers, valves, or external venting, all required for long-term, pulsatile pumps. Their small size allows a simpler implantation procedure, decreasing surgical trauma, allowing implantation in smaller patients and reducing complications. These devices may be more reliable, thus decreasing mortality from device failure and replacement (Pitsis et al. 2007).

Newer generation implantable long-term LVADs evacuate blood from the left ventricle and pump it to the systemic circulation, in a continuous flow pattern. Continuous blood flow is generated by axial flow pumps with an impeller rotating at a high speed, or by sophisticated centrifugal pumps with rotors spinning at lower speeds. Devices with mechanical rotor bearings have been characterised as second generation LVADs, while devices

with bearingless rotors based on magnetic, hydrodynamic or hybrid levitation have been characterised as third generation LVADs. The most commonly-used second generation devices are axial flow LVADs, while third generation devices have centrifugal or axial flow pumps (see table 1).

#### Bridge to Recovery (BTR)

Since the early days of long-term LVADs as BTT devices, it was noted that the supported heart sometimes recovered to such an extent that heart transplantation was cancelled. The first study to prospectively quantify the rate of heart recovery was by the LVAD working group (Maybaum et al. 2007). They prospectively studied 67 patients supported with different devices as BTT and noticed recovery sufficient to allow explantation of the device in 9% of the patients. This patient population included patients with acute and advanced chronic heart failure (CHF). In the advanced CHF population the recovery rate sufficient to allow explantation was only 4% (2 out of 46 patients).

The Harefield group published a protocol of BTR based on clenbuterol (Birks et al. 2006). Clenbuterol was administered to prevent myocardial atrophy after patients supported with LVADs also received optimal medical treatment with lisinopril, carvedilol, spironolactone, and losartan. The group achieved an excellent recovery rate that seems to be sustained during follow-up, which has exceeded the four-year mark.

It seems that apart from the cases where "spontaneous" recovery of the heart function in patients supported with LVADs happens to occur, these devices can be used electively as platforms that enable the application of therapies that promote reverse remodeling of the failing heart to the extent to safely allow discontinuation of the MCS. This is a very appealing application of this kind of technology and a significant advantage over heart transplantation.

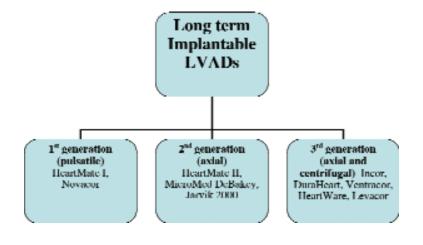


Table 1: Currently used 1st, 2nd and 3rd generation left ventricular implantable devices.



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#### Echocardiography

This painless, non-invasive test uses sound waves to create 2D images of the cardiovascular system. New systems also produce 3D images. With the help of Doppler ultrasound it also produces information about the velocity of blood flow in the heart and measures heart valve function. A transducer is placed on the chest wall of the patient in order to transmit and receive acoustic signals. The size of all four heart chambers is measured and left and right heart chamber function is assessed. Echocardiography is simple, can be performed quickly, and is radiation- and risk-free. Echo machines are mobile and can hence be used everywhere. However, image quality is insufficient in some patients.

#### Stress Echocardiography

Stress can be used to detect or exclude stenoses of the coronary arteries and can be performed on a treadmill or a bike. In patients who cannot exercise, drugs can be used as alternative stressors. A properly performed stress echocardiogram with a normal result excludes a significant stenosis of a coronary artery with a high level of confidence. The main limitation of the test is its dependence on a well-trained operator. In some patients, image

#### **EVALUATING HEART DISEASE**

#### The Role of Cardiac Imaging

Coronary artery disease (CAD) is the leading cause of mortality in the industrial world. Cardiac imaging is essential to establish the diagnosis and severity of CAD and to determine the potential risk of future cardiovascular events. In patients with suspected CAD, evaluation of patient history will reveal the presence of cardiac risk factors and typical symptoms. An ECG should be performed in all patients with suspected CAD. This article explores the different methods for imaging cardiac diseases, reviews the pros and cons of each method.

quality is not sufficient to perform a stress echocardiogram.

#### Trans-Oesophageal Echocardiography (TEE)

A TEE can be performed with the same machine as a standard echocardiogram, but it requires a different probe. During this test, the patient is sedated. The small probe, containing an ultrasound transducer at its tip, is placed down the patient's oesophagus. Being close to the heart, the ultrasound has only a small way to travel.

Structures including both atria, the atrial septum, the left atrial appendage, the

heart valves, and the aorta of the heart can be visualised with more detailed images than with the standard trans-thoracic echocardiogram. Heart valve abnormalities can be seen with high image quality. The limitation of the test is its semi-invasive nature but the risk of the test is very low. Despite sedation the test may be uncomfortable for some patients. The coronary arteries cannot be visualised.

#### Nuclear Imaging

Stress myocardial perfusion imaging with single-photon computed tomography (SPECT) uses radioactive tracers to gather information about regional blood flow, coronary artery perfusion and ventricular

	CAD	Valvular HD	Myocardial HD
Echocardiography	+	+++	++
Stress Echocardiography	+++	+	-
SPECT	+++	-	-
MRI	++	+	+++
СТ	++	+	-
Cardiac catheterisation	+++	++	+

Table 1. Utility of different imaging modalities in different heart diseases. HD denotes heart disease. +++ = very useful; ++ = useful; += of limited use; -= not useful.



Image 1: TEE.

Panel A: TEE in a patient with a stenosis of the aortic valve. The calcified leaflets and the reduced opening are clearly shown. LA: left atrium. RA: right atrium. AC: calcified aortic cusps. AVA: aortic valve area at maximal opening.

Panel B: TEE in a patient with a mitral valve prolapse and severe mitral regurgitation. The posterior leaflet of the mitral valve is displaced towards the left atrium. LA: left atrium. LV: left ventricle. AV: aortic valve. PML: posterior mitral leaflet. AML: anterior mitral leaflet.

Panel C: same patient as in Panel B. with colour Doppler: the regurgitant jet from the left ventricle through the mitral valve in the left atrium. RF: regurgitant flow.

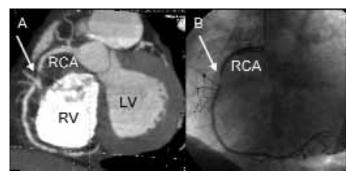


Image 2: Noninvasive coronary angiography with 16-row computed tomography.

Panel A: Reconstructed image of the right coronary artery with high grade stenosis (white arrow), confirmed by cardiac catheterization (panel B). RCA: Right coronary artery. RV: Right ventricle. LV: Left ventricle.

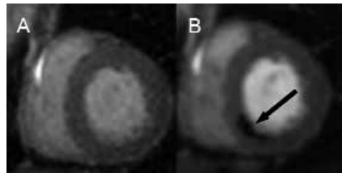


Image 3: Cardiac MRI. Short axis images of the left ventricle.

Panel A: Stress perfusion MRI at rest.

Panel B: Stress perfusion MRI after adenosine. An area of the inferior wall is hypoperfused and remains darker than the adjoining myocardium (arrow) indicating the presence of a stenosis of the right coronary artery.

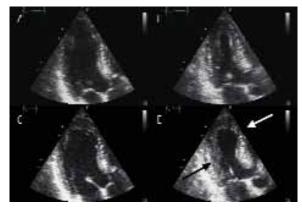


Image 4: Stress echocardiography. The left ventricle is shown in the long axis view.

Panel A: Relaxed muscle at rest.

Panel B: Contracted muscle at rest. Normal contraction of all visible parts.

Panel C: Relaxed muscle at peak stress.

Panel D: Contracted muscle at peak stress: normal contraction and thickening of the inferior wall (black arrow). Reduced contraction (hypokinesia) of the anterior wall and the apex (white arrow) indicative of a stenosis of the left anterior descending coronary artery.

function and has a high diagnostic accuracy in patients with suspected CAD. In patients incapable of exercise, pharmacologic stress SPECT has comparable accuracy. A normal perfusion scan is associated with an excellent outcome. With newer radioactive tracers the size and function of the left ventricle can be measured. The primary disadvantages are radiation exposure and the expense of the procedure.

#### Coronary Angiography and Left Heart Ventriculography

Coronary angiography is an invasive method of visualising the coronary arteries. In most cases, a catheter is inserted in the groin and pushed to the heart. The coronary arteries are filled with contrast media so the internal lumen of the coronary tree can be seen and all stenoses can be demonstrated. The outer parts of the coronary arteries can't be seen as only contrast media or calcified structures appear on the radiographic images. Image resolution of the coronary tree is higher than with any other method.

If a stenosis or occlusion of a vessel is found, an intervention can be performed during the same session. In patients with acute myocardial infarction with elevation of the ST-segments in the ECG, immediate coronary angiography can save lives. The left ventricle can be filled with contrast medium and contractions of the left ventricular myocardium demonstrated.

SPECT • function coronal coro	transportable machine onal information about ary arteries onal information about	<ul> <li>no information about coronary arteries</li> <li>dependence on good visibility</li> <li>dependence on good visibility</li> <li>radiation exposure</li> </ul>
Stress echocardiography  • function coronals  SPECT  • function	onal information about ary arteries onal information about	, ,
corona SPECT • functi	ary arteries onal information about	, ,
		radiation exposure
	ary arteries	
	onal information about ary arteries	more expensive
·	nologic information about ary arteries	<ul><li>radiation exposure</li><li>contrast material in patients with kidney failure</li></ul>
coron	nologic information about ary arteries ention possible	<ul><li>invasive</li><li>radiation exposure</li><li>contrast material in patients with kidney failure</li></ul>

Table 2. Advantages and disadvantages of different imaging modalities in patients suspected of having CAD.

The disadvantages of coronary angiography are radiation, the need for contrast media and its invasiveness.

#### Magnetic Resonance Imaging

Cardiac MRI is the most accurate technique for evaluating ventricular size and function. It is useful in the evaluation of cardiac masses and congenital heart disease.

Cardiac MRI angiography is a standard technique for imaging the aorta and the large vessels. After administration of gadolinium-containing contrast material, myocardial infarction scars can be detected with a sensitivity unparalleled by any other technique and characteristic patterns of contrast enhancement can be visualised in a variety of myocardial diseases like amyloidosis and hypertrophic cardiomyopathy.

The disadvantages of cardiac MRI are the expense and the need for contrast material although MR contrast agents are not nephrotoxic. However, serious side-effects were recently described in patients with renal failure.

#### Computed Tomography

With CT of the heart, either coronary calcifications can be measured or a noninvasive coronary angiography can be performed. No contrast material is needed. The amount of coronary artery calcium is indicative of the atherosclerotic plaque burden and is associated with the cardiac prognosis. However, the amount of coronary calcium does not correlate with the focal stenosis severity of a given lesion and is therefore unhelpful in predicting the necessity of an intervention.

High resolution noninvasive coronary angiography is now feasible. 64-slice multi-detector CT has good sensitivity and a high specificity for the exclusion of high-grade coronary stenoses.

Disadvantages of CT angiography are high radiation exposure and the need to administer contrast media.

#### Summary

Echocardiography is the main noninvasive imaging method in heart disease. It is quickly performed, relatively cheap and has no side effects. A good echocardiogra-

phy laboratory is thus mandatory in all cardiology departments.

In patients suspected of having CAD who have an ambiguous stress-test or are not able to exercise stress echocardiography or SPECT myocardial perfusion imaging should be performed. Which technique is performed depends on local expertise and availability. Stress echocardiography has the advantage of not being accompanied by radiation exposure. Expertise in at least one of the techniques should be maintained in all cardiology departments. With coronary angiography, an optimal morphologic diagnosis can be established which may be the basis for an intervention performed in one session.

In the last few years, cardiac MRI and cardiac CT have shown great promise in patients with CAD and other heart diseases. Cardiac MRI has been shown to be very useful in a variety of myocardial diseases. Cardiac CT is able to visualise coronary artery stenoses with high accuracy. However, their role in patients with suspected CAD and other heart diseases has yet to be defined precisely.

### Industry NEWS

#### Pfizer to Cancel 'Misleading' US Ad Campaign

Pfizer has announced the cancellation of its widely-known US ad campaign which features artificial heart pioneer Robert Jarvik as a spokesman for its cholesterol drug Lipitor. The campaign had come under scrutiny from a Congressional committee examining consumer drug advertising that asked if the ads misrepresented Dr. Jarvik and his credentials. Although he has a medical degree, Dr. Jarvik is not a cardiologist and is not licensed to practice medicine.

#### US FDA Advises Caution on Baxter's Multiple-dose Vial Heparin

Baxter Healthcare Corporation has temporarily stopped manufacturing multiple-dose vials of the injectable blood-thinning drug heparin due to reports of serious allergic reactions and hypotension in patients who receive high bolus doses of the drug.

Adverse events have not been seen in other uses of heparin involving lower doses or administration over a longer period of time. Healthcare providers are advised to use an alternate

source of heparin or other bloodthinning drug when possible.

When only Baxter product is available:

- Administer the heparin as an infusion rather than a bolus;
- Use the lowest dose necessary at the slowest infusion rate acceptable to obtain the desired clinical effect;
- Closely monitor the patient for adverse events, particularly hypotension and signs and symptoms of hypersensitivity and ensure that resuscitation equipment is available, and
- Consider pre-treatment with corticosteroids though it is unclear if this is effective.

#### Avista Capital Gains FDA Exclusivity Extension for Cardiolite

The FDA has granted paediatric exclusivity for studies conducted

on Cardiolite (kit for the preparation of technetium Tc99m sestamibi for injection). This grant extends the marketing exclusivity of Cardiolite for an additional six months beyond patent expiration, the company said.

## St Jude Medical Announces Renewal of through December 2010 and Purchase Agreements covers all existing purchasing

St. Jude Medical has renewed its product agreements with HealthTrust Purchasing Group. The renewal will extend

through December 2010 and covers all existing purchasing agreements, including St. Jude Medical's complete line of cardiac rhythm management, atrial fibrillation, cardiac surgery and cardiology products.

#### Pfizer's Sutent Under Scrutiny

US researchers at the Stanford University School of Medicine in California have found that 15% of patients who took Sutent, a pill used to treat kidney and stomach cancers, developed heart failure.

Sutent, made under the generic name 'sunitinib' by Pfizer, has

also been shown to damage heart cells. While heart failure is serious, it can be treated with a variety of drugs. When caused by drugs, stopping the medication usually clears up the problem. Sutent works by starving tumours - it stops them from growing blood vessels to feed themselves. It is being widely tested for the treatment of several other cancers.

#### BR-102 Plus Validated by British Hypertension Society

The SCHILLER BR-102 plus non-invasive ambulatory blood pressure monitor was validated according to the International Protocol for validation of blood pressure measuring devices in adults introduced by the Working Group on Blood Pressure Monitoring of the European Society of Hypertension.

The conclusion of the protocol states that the obtained results presented in tables and graphics satisfy the requirements of the international protocol. The accurate readings of systolic and diastolic blood pressure when operating either in auscultatory or in oscillometric modes during the evaluation procedure enable SCHILLER BR-102 plus to be recommended for ambulatory blood pressure measurement in clinical practice.

#### Cardiovascular Systems, Inc. Files Registration Statement for IPO

Cardiovascular Systems, Inc. has filed a registration statement for

a proposed initial public offering (IPO) of its common stock. The number of shares to be offered and the price range for the offering have not been determined. The offering will be made only by means of a prospectus.

## 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. 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 resolu-

tion 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 x 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 editorial@cardiologymanagement.eu.

Thank you,

The CARDIOLOGY Management Editorial Team

#### CeloNova BioSciences Introduces New Coronary Stent

CeloNova BioSciences has announced results from the ATLANTA study of the CATA-NIA(TM) Coronary Stent System with NanoThin Polyzene(R)-F at the 20th Annual International Symposium on Endovascular Therapy (ISET). Dr. Corrado Tamburino, principal investigator

for the ATLANTA study, stated, "I perform many angioplasties each day, and I am impressed by the performance of this stent in a very complex patient population. No thrombosis. Low binary restenosis. No MIs." The CATANIA(TM) Stent System with NanoThin Polyzene(R)-F has completed CE marking and is available for sale anywhere the CE mark is accepted.

#### EVICEL™ Fibrin Sealant Approved For General Haemostasis In Surgery

ETHICON has announced that the US FDA has granted an expanded indication for EVI-CEL<sup>TM</sup> Fibrin Sealant (Human). The product is the first fibrin

sealant to be indicated as an adjunct to haemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques is ineffective or impractical.

EVICEL™ is the only all-human plasma-derived fibrin sealant commercially available in the US.

#### Boston Scientific Announces Approval of New Cardiac Devices

Boston Scientific Corporation announced CE Mark approval for its COGNIS(TM) cardiac resynchronisation therapy defibrillator (CRT-D) and TELIGEN(TM) implantable cardioverter defibrillator (ICD). These devices treat heart failure and sudden cardiac death. The COGNIS CRT-D and

the TELIGEN ICD are among the world's smallest and thinnest high-energy devices at 32.5cc and 31.5cc respectively, while less than 10mm thick. Both offer features including extended battery longevity, self-correcting software and improved programming technology. Both devices also offer SafetyCore(TM), a feature that in the event of a system error provides lifesaving shock therapy and basic pacing functionality.

#### eCardio Diagnostics Launches Cardiac Event Monitoring Features

eCardio Diagnostics will release several new product features and services to enhance its cardiac diagnostic product line. Among eCardio's new product releases is the eTimer<sup>TM</sup> Automatic Data Capture feature to its cardiac event monitor, the eTrigger<sup>TM</sup> AF 920. This allows for the capture

and monitoring of ECG data at pre-defined and programmable intervals throughout the patient's cardiac monitoring protocol. The function expands the flexibility of eTrigger for its use in various patient therapy or clinical study applications such as treatment or device monitoring, post-ablation follow-up, drug titration, safety and efficacy assessments, and the documentation of normal cardiac function.

#### FDA Approves Medtronic's Drug-Eluting Stent

Medtronic, Inc. has announced that it has received approval from the US Food and Drug Administration (FDA) for the Endeavor® Zotarolimus-Eluting Coronary Stent System to be used in the treatment of coronary artery disease.

The Endeavor data encompasses the largest, most wide-ranging

patient population submitted to the FDA in support of a drug-eluting stent, including more than 4,100 patients, followed up for as long as four years. This extensive clinical research has shown that Endeavor provides a consistent and sustained reduction in the need for repeat procedures compared to a bare-metal stent, while also maintaining an excellent safety profile. The Endeavor stent is the first new drug-eluting stent approved by the FDA since 2004.

#### Medtronic Foundation Funds US School Programmes

The Medtronic Foundation announced new grant guidelines for its HeartRescue programme, allocating funding priority to school programmes that educate students about sudden cardiac arrest and prepare them to act in an emergency.

To increase the number of bystanders trained in CPR and AED use, the 2008 HeartRescue

programme will focus US grants on schools, school districts, government agencies, and non-profit organisations that develop comprehensive school-based programmes to prepare people to recognise SCA and take action.

Guidelines for Canada and Europe will also include schoolbased initiatives, as well as funding first responder and public access defibrillation efforts, to meet the different needs of each country.

#### Key Upcoming Events & Congresses

#### **JUNE 2008**

3 - 4 Neonatal & Paediatric Cardiac Intensive Care Course London, United Kingdom

http://www.ich.ucl.ac.uk/education/short\_courses/courses/2T27

Course in Cardiogenesis and Congenital Cardiopathies 7 - 10 Bertinoro, Italy

http://www.eurogene.org

14 - 17 Heart Failure 2008

Milan, Italy

http://www.escardio.org/congresses/HF/HF2008

14 - 19 Hypertension 2008: 22nd Scientific Meeting of the International Society of Hypertension Berlin, Germany

http://www.hypertension2008.com

19 - 21 ACCF/SCCT Coronary CTA Practicum

Washington DC, US

http://www.acc.org

6th Annual Cardiovascular MR and CT Conference

Washington, DC

24 - 27 Endothelium, Vasoactive Factors and Inflammation (EHDF) Symposium

Tampere, Finland

http://www.edhf2008.org

#### JULY 2008

3 - 6 The World Congress on Controversies in Cardiovascular Diseases (C-Care) Berlin, Germany

http://www.comtecmed.com/ccare/

9 - 11 3rd Annual Symposium on Integrated Biomarkers in Cardiovascular Diseases Seattle, United States

http://www.ibcvd.org

18 - 20 Clinical Applications of Advanced Echocardiography Essen, Germany

http://www.mayo-essen.com

#### **AUGUST 2008**

21 - 23 Brazilian Society of Cardiology Annual Congress

Washington, DC

http://www.cardiol.br/conheca/english/

European Society of Cardiology Congress 2008

Munich, Germany

http://www.escardio.org/congresses/esc\_congress/

#### SEPTEMBER 2008

18 - 20 2008 Heart Valve Summit

Chicago, IL, US

9th International Dead Sea Symposium on Cardiac Arrhythmias and Device Therapy Tel-Aviv, Israel

http://www.kenes.com/arrythmia

24 - 27 6th World Stroke Congress

Vienna, Austria

http://www.kenes.com/stroke2008

5th Global Cardiovascular Clinical Trialists Forum 25 - 27

Cannes, France

http://www.globalcvctforum.com

26 – 27 6th Advanced Symposium on Congenital Heart Disease in the Adult Thessaloniki, Greece

http://www.achd2008.com



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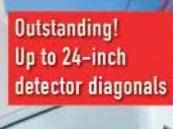
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