



CARDIOLOGY MANAGEMENT

Volume 3 - Issue 1, 2009

COST-EFFECTIVENESS IN THE CARDIOLOGY DEPARTMENT

Evidence-Based Purchasing, Cost Analysis Methods & More

- The Role of the Nurse in a Multidisciplinary Team
- Quality Standards in Paediatric Echocardiography
- Leadership & Coaching for Healthcare
- Telecardiology in Italy



GE is making a new commitment to healthcare

We call it **healthymagination**

At GE, we believe what's needed, right now, is a new mindset that embraces that health is everything. Just as we delivered innovation in environmental technology with ecomagination, healthymagination will change the way we approach healthcare, with over 100 innovations all focused on addressing three critical needs: **lowering costs, touching more people and improving quality.**

Yes, costs need to be lowered, while still delivering the best technology possible. GE's Electronic Medical Records give doctors the information they need almost instantly and could save billions in costs over the next 5 years.



Reduce Costs



Increase Access

Access to healthcare should be more available and not determined by where you live. Equipment like GE's MAC 800 brings lifesaving ECG technology to patients in a unit smaller than a backpack, accessible to the most remote hospitals and clinics in the world.

Quality healthcare empowers more people through early detection and a higher level of care at home. As people age or face chronic conditions, they need innovations like Home Health technologies that remotely monitor their well-being so they can live independently.



Improve Quality

To learn more visit,
www.healthymagination.com



GE imagination at work

Editorial

Dear Readers,

For two thousand years, the oath of Hippocrates has bound its proponents to uphold the highest of professional standards in treating patients. This inviolable commitment continues today and clearly delineates the duties of our vocation.

Nevertheless, much has changed today in comparison with ancient medicine. Modern medical science has progressed tremendously, while also gaining a dependency on complex and costly procedures. Simultaneously, the overall politics of social care have moved far away from the old realities, when there was minimal social organisation and protection.

The new realities inevitably affect the way modern medicine is practiced. Modern methods of calculating the incremental cost-effectiveness ratio (ICER) per quality-adjusted life year (QALY), or the number needed to treat (NNT) in order to save one life, increasingly predominates in the evaluation of medical practice. A typical example is that in industrially developed countries a somewhat arbitrary number, of around 40,000 euros, represents the financially acceptable threshold per QALY.

It is natural that, especially in a time of economic recession, the high ideals of the Hippocratic oath might fall on hard times, since the vertiginous cost of applying the whole spectrum of advanced biotechnology is often hard to attain for those operating within a specific budget. This can lead to an intractable dilemma, and not infrequently to confrontation between physicians and managers of the institutions that comprise the healthcare system. The latter maintain that they are working for the correct management of the invaluable financial reserve that the state makes available for health; the former insist that pride of place, practically and philosophically, must be given to the health and life of the patient.

This confrontation does not have winners and losers, only compromises that acknowledge realities on both sides. Firstly, physicians should become more familiar with the cost-effect relation. They must understand that resources are finite and get to know at least the simpler concepts in the jargon of health economics. They must operate optimally, having respect for taxpayers' money.

Managers, on the other hand, need to understand better that they are in charge of areas that are particularly special and sensitive, quite unlike industrial or similar organisations. They must prove that they are ready to adopt, fight for, and aspire to the utilisation of new techniques and therapies, regardless of the cost, as long as they are effective. Unfortunately, this last is often not very apparent to physicians.

Finally, governments must contribute, by demonstrating that their policies are aimed at supporting the ultimate goal—the health of their citizens. After all, everything is based on a central political philosophy, that should this orientation be for the wellbeing of their citizens, then funds will be found.

Yours faithfully,

Panos E. Vardas, MD, PhD
Professor of Cardiology



Editor-in-Chief
Professor Panos Vardas

How can we improve the workflow in our cath lab?

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

How can we improve the reporting process and report availability?

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

As part of the *syngo*[®] Suite, *syngo Dynamics* is a multi-modality, dynamic image processing and archiving system, using evidence-based reporting to help improve the efficiency of your clinical procedures. The scalable solution effectively integrates patient digital imaging information throughout the cardiology department and beyond – providing patient images and data when and where they are needed. *syngo Suite*. Living workflow intelligence.
www.siemens.com/syngo-suite +49 69 797 6420

Answers for life.

SIEMENS

Editor-in-Chief

Prof. Panos Vardas

Editorial Board Members

Prof. Gunter Breithardt, Germany

Prof. Michele Brignole, Italy

Prof. Hugo Ector, Belgium

Prof. Michael Glikson, Israel

Prof. Peter Kearney, Ireland

Prof. Alexandras Laucevicius, Lithuania

Dr. Nick Maniadakis, Greece

Prof. Chu Pak Lau, China

Prof. Fausto J. Pinto, Portugal

Prof. Piotr Ponikowski, Poland

Prof. Silvia G. Priori, Italy

Prof. Amiran Revishvili, Russia

Prof. Massimo Santini, Italy

Prof. Ernst R. Schwarz, US

Prof. Udo Sechtem, Germany

Prof. Dan Tzivoni, Israel

Prof. Alec Vahanian, France

Dr. Rob van den Oever, Belgium

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

LEGAL DISCLAIMER

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

- 1 Editorial
- 6 EU News
- 47 Industry News

COVER STORY
Cost-Effectiveness

- 8 Cost-Effectiveness & Cardiac Imaging: Combined Approach to Patient Management May Yield Substantial Savings
Prof. Claudio Marcassa, Prof. Pier-Luigi Temporelli
- 11 Access to Technologies: A Matter of Cost or of Effectiveness?
Prof. Giuseppe Boriani, Dr. Alessandro Marziali, Dr. Mauro Biffi, Dr. Cristian Martignani
- 13 Cost-Effectiveness Aspects of Defibrillators: Decreasing the Financial Burden
Prof. Bharat K. Kantharia
- 15 Evidence-Based Purchasing in Cardiology: Cost-Effective Healthcare Technology Assessments
Dr. H. Cole, L. Bowers
- 18 Calculating Your Costs: Principals of Economic Evaluations
Dr. H. Mistry

FEATURE

- 21 Increase in the Use of Portable Ultrasound by Cardiologists
Diane Wilkinson
- 22 The Role of the Nurse in a Multidisciplinary Team Setting & the EUROACTION Trial
Catriona Jennings
- 24 Quality Standards in Paediatric Echocardiography
Dr. Mark Lewin, Dr. Joel Lester
- 28 The Effectiveness of Nurse-Led Clinics
Tammy Page, Tiffany Conroy
- 30 Multidisciplinary Approach to Syncope
Dr. L. A. Serrano

CARDIOLOGY LEADERS

- 32 Interview with Prof. P. Brugada

HEALTHCARE ECONOMICS

- 34 Leadership and Coaching in the Healthcare Arena: What You Need to Know
Franz Immer

COUNTRY FOCUS: CARDIOLOGY IN ITALY

- 36 Overview of the Healthcare System
- 38 Healthcare IT & eHealth in Italy
T. Sheshabalya
- 40 Telemedicine Applications in Cardiology
Dr. Paolo Zanaboni
- 43 Italian Hospitals and the New Managerialism
E. Cantu

CONFERENCE AGENDA

- 48 Overview of Upcoming Congresses and Meetings

ITA@ NETWORKING

The IT @ Networking Awards 2009 will select outstanding European healthcare IT solutions in hospitals and healthcare facilities and bring them to the pan-European stage.

WINNING PROJECT
GETS EXTENSIVE
PRESS COVERAGE
AND €5,000 CASH

WHERE AND WHEN

Brussels, the centre of European decision-making, will be the location for the IT @ Networking Awards 2009 (*IT @ 2009*). It will be held from 29 - 30 October 2009 during the European Summit in October at Square, Brussels' hottest new meeting centre ensuring international attention.

WHO

The event will be organised by the *European Association of Healthcare IT Managers* (HITM) and the *European Association of Hospital Managers* (EAHM), the largest interest representations of their kind in Europe.

The attendee roster will include Cardiologists, hospital CEOs, CIOs, CMIOs, hospital and healthcare IT managers, other physicians with an interest in IT, members from European and national institutions whose mandates cover healthcare IT and members from the pan-European Press.

WHY

Behind its fragmented façade, European healthcare IT includes a number of world-class jewels: cutting edge IT solutions that meet real-world challenges, efficiently and cost-effectively, and not rarely, in an elegant fashion. Unfortunately, many such jewels remain unknown to the outside world – not just to the general public, but ironically, to the healthcare IT community as well.

So too do their designers and architects, unsung heroes who have often invested their creative talents, and dedicated months and years of hard work – to create and build something good, something better, all the way through to the very best. But many such efforts extend beyond job descriptions, stretch far above the call of duty.

These pioneers need recognition! Their stories will inspire others. The lessons they have learned can help both avoid mistakes and transform healthcare IT challenges into opportunities, into "Made-in-Europe" success stories. This is the goal of *IT @ 2009*.

HOW

HITM and EAHM believe that peers will make the wisest decisions in respect to their own needs. As far as healthcare IT is concerned, the Associations consider it to be self-evident that senior healthcare professionals will know what is the best solution for them and their challenges they face.

To use familiar terminology for IT professionals, *IT @ 2009* is built on the principles of best-of-breed and peer-to-peer networking.

An on-the-spot, one-person = one-vote novel voting electronic system will be used to enable attending CEOs, CMIOs, CIOs, hospital and healthcare IT managers as well as department heads to make their choices. Only they are eligible to vote.

ORGANISERS:



European
Association of
HEALTHCARE IT
MANAGERS



MEDIA PARTNERS:

HEALTHCARE IT
MANAGEMENT



G AWARDS 2009

ROLLOUT: FROM MINDBYTE TO WORKBENCH

FIRST DAY: MINDBYTE

All successful submissions for the *IT @ 2009* will be allocated 10 minutes for a Mindbyte (a short presentation) on what differentiates their solution and makes it special.

SECOND DAY: WORKBENCH

Finalists of the *IT @ 2009* will be given 45 minutes to provide an in-depth presentation, followed by a 1/4 hour Q&A session with the specialist audience.

THE IT @ Networking Awards 2009 CEREMONY

Out of the finalists, the 3 top rated IT solutions will be awarded a prize.

The winning project will:

- receive the IT @ Networking Awards 2009 trophy;
- have a detailed presentation of their solution in Europe's leading healthcare management media, and
- be awarded a cash prize of Euro 5,000.

REGISTRATION

- Full Members of the European Association of Healthcare IT Managers
- Other CEOs, CMIOs, CIOs, hospital and healthcare IT Managers
- Other industry professionals not employed by a healthcare facility

Until 4 September

Euro 200,-
Euro 300,-
Euro 800,-

From 5 September

Euro 300,-
Euro 400,-
Euro 1000,-

WHO SHOULD PARTICIPATE

Developers of imaginative, innovative healthcare IT solutions. Solutions can be built on both COTS as well as bespoke designs. However, all entries have to demonstrate a considerable degree of customisation and show ingenuity. All entries must be already implemented in at least one site.

SUBMISSION DEADLINE

We are sure that your project will make a difference. Submissions must be received by **25 September 2009** and must be entered through www.conftool.com/itawards2009/

For further information on IT @ Networking Awards 2009 or for your project submission please visit our website www.hitm.eu, contact our General Secretariat via email awards@hitm.eu or call +32 / 2 / 286 8501.

REGISTER NOW!

EC-FUNDED E-HEALTH STUDY LOOKS AT PROGRESS AND BARRIERS

A new study funded by the European Commission is assessing the progress made to date, towards the realisation of European e-Health Action Plan goals. Good practices and lessons learned constitute the study's key elements. The results will be fed into policy recommendations for further accelerating e-Health implementation.

The study has been assigned to a consortium consisting of empirica Communication and Technology Research (Germany), The National Institute for Health and Welfare (Finland), Time.lex (Belgium), Prof. Denis Protti of the University of Victoria (Canada) and University College, London (UK), and EMC Consulting Group (Belgium). The European Commission and EU Member States have long recognised the potential of ICT-enabled applications to improve citizens' health and healthcare delivery as well as public health services or medical research.

The e-Health Strategies study will take a closer look at policy documents, concrete e-Health implementations and national-level legal and regulatory as well as administrative support mechanisms. In addition, it will also deal with financial and reimbursement issues. The research effort draws upon earlier projects funded by the European Commission. In particular, these include the e-Health ERA study and the "Legal Framework of Interoperable e-Health in Europe" study. A network of National Correspondents will raise data on new developments and validate existing information for each country.

The final project report – based on individual country briefs - will provide a summary of e-Health progress on a European level and information regarding the spectrum of e-Health solutions available in each country, the degree of administrative and legal support and

financial incentives for promoting the use of e-Health applications.

For further information, please visit: www.ehealth-strategies.eu

Results Published on EU RFID Project

The first results of the EU's RFID (Radio Frequency Identification) and Health project have been published. The report presents the findings of the first phase of a study to identify the policy options that can help the development and application of RFID in healthcare. The objectives of the study were:

- To identify and discuss the most relevant areas for deployment and use of RFID in healthcare;
- To identify the most important enablers, obstacles and uncertainties, and
- To discuss other alternatives to RFID technologies.

The report found that tracking is the key RFID-enabling function in use. Applications include identification and authentication of patients as well as automatic data collection and transfer in clinical trials.

The key barriers and obstacles to RFID's wider-scale implementation, include:

- Direct RFID costs;
- Privacy, security, data integrity and legal issues;

- Technical issues;
- Operational/managerial challenges, and
- Cultural and ethical concerns.

The Prague Declaration: Spotlight on e-Health

The e-Health Conference 2009 in Prague (Health for Individuals, Society and Economy) has been followed by the release of the Prague Declaration. This emphasises the progress already made in e-Health by both Member States and the European Union. It also notes that the benefits of e-Health for a safe and efficient health sector have long been recognised by expert stakeholders.

The Prague Declaration states that the benefits of e-Health applications and services must be enhanced and evenly distributed among all stakeholders, as follows:

1. Benefits for Individuals, Society and the Economy

For individuals, e-Health can increase quality and effectiveness of services. It is of immense benefit to those with chronic illnesses, and can improve continuity of care and facilitate cross-border healthcare. For society, e-Health is about interoperability, e-literacy and the accessibility of new technologies. It is also a great opportunity for research and development with high growth and innovation potential. As far as the economy is concerned, e-Health can offer enormous savings by enhancing reach, access and effectiveness.

2. Call for Building Further on Achievements

Considerable progress has already been made since the last e-Health conference, but the general consensus is that progress must not stop there. It has been decided to move forward and concentrate on the areas important for the full utilisation of e-Health potential. Consequently, EU Member States have been encouraged to take actions concerning telemedicine, interoperability and exchange of best practices.

3. Telemedicine Deployment

The November 2008 communication from the Commission on telemedicine highlights areas for improvement and provides an action plan for the full exploitation of opportunities offered by telemedicine. Both patients and healthcare professionals must build their confidence in telemedicine services.

“Harmonised standards would facilitate access to healthcare for all EU citizens, wherever they happen to work or travel”

In order to increase the level of confidence, technical issues needed to be resolved and legal clarity must be achieved. Another challenge facing telemedicine is market development. Once these challenges are overcome within Member States the market will become less fragmented and not limited to one-off and small-scale projects.

4. Interoperability and the M403 Mandate

In order for e-Health to expand and reach its full potential a common set of stan-

dards for electronic health records, patient summaries, emergency data and other services must be developed. There is a clear lack of interoperability, which has already been highlighted in the existing EU action plan on e-Health.

Harmonised standards would facilitate access to healthcare for all EU citizens wherever they happen to work or travel. Key elements in interoperability are semantic and technological standards. The Declaration states that the implementation of the e-Health Interoperability Standards Mandate M403 is an initiative that should be widely supported for enabling interoperability of e-Health systems and services in Europe.

5. European Cooperation and Exchange of Best Practices

e-Health high-level conferences are great opportunities to exchange best practices between Member States. Studies have

shown that there is a large gap between Member States and between readiness and actual use of e-Health. Although most healthcare professionals are now using IT, there is room for improvement concerning the interconnectivity of electronic networks of different health actors. Further development is therefore required.

Next Steps on the Agenda

In order to facilitate the development, implementation and use of new e-Health services the declaration highlights three focus areas:

1. Fulfilling Existing Strategic Goals and Developing New Ones

The Member States declare their intent to fulfil the goals of the i2010 initiative, e-Health action plan and specific national strategies already in place to promote e-Health in the EU.

2. Patient Safety and Empowerment

IT usage in the health sector has already had a positive impact on patient safety. Future actions must include strengthening patient involvement through the communication of targeted patient safety policies and solving legal and ethical issues. Privacy and data protection must also be high priority, including developing a common approach to optimising existing directives on data protection and privacy.

3. Governance Structure for e-Health

Due to its increased importance and use, arrangements for Europe-wide governance are needed. This will be discussed by all Member and partner European States in order to achieve interoperability and facilitate faster deployment so that patient safety and continuity of care is ensured within Member States as well as on a cross-border level.

Conclusion

The Prague Declaration serves as a call for action on building an e-Health area for European citizens. Member States and the Commission must work together to build this area, which will enable all citizens' access to healthcare. National strategies must be adapted so that individuals, society and economy receive the benefits of e-Health and Member States must work together to create a European-wide governance structure to facilitate the implementation of new services as well as the removal of existing barriers.

For more information, please visit: www.ec.europa.eu/information_society/newsroom/cf/document.cfm?action=display&doc_id=590



COST-EFFECTIVENESS & CARDIAC IMAGING

Combined Approach to Patient Management May Yield Substantial Savings



AUTHORS

Dr. Claudio Marcassa (above, left)
Dr. Pier Luigi Temporelli
S. Maugeri Fnd, IRCCS
Scientific Institute of Veruno
Department of Cardiology
S. Maugeri Foundation
Veruno, Italy
claudio.marcassa@fsm.it

Coronary artery disease (CAD) is presently the most common cause of death in industrialised countries. Consequently, diagnosis and treatment of cardiovascular diseases represents a large drain on resources. In this challenge, stress imaging techniques represent a cornerstone in the management of stable patients and have demonstrated, over the years, their role as an effective gatekeeper over the use of more invasive and sophisticated techniques. However, this is obtained at an excessive cost to society.

From a healthcare policy perspective, the value of strategies for the management of patients with chest pain should rely not only on diagnostic accuracy, the absence of side-effects, and the cost of the procedure, but also on the pre-test probability of significant CAD, the cost of additional tests and treatments that the results may

induce, the costs of events that may be driven by a subsequent treatment (i.e. a coronary angioplasty), and the quality of life of the patients. Unsurprisingly, cost-efficiency analyses are increasingly seen as solutions for integrating both economics and efficacy into one indicator to be used to compare different therapies, technologies or global clinical strategies relative to one another.

Cost-Efficiency Analysis in Clinical Diagnosis

The importance of a cost-efficiency analysis in clinical diagnosis depends, in general, not only on the costs related to the choice of the initial diagnostic technique, e.g. direct catheterisation versus stress imaging techniques, but also on the

intermediate pre-test probability of CAD, strategies including MPS have consistently shown to be more cost-effective than the conventional exercise ECG. In addition, a management strategy based on MPS data results in 23% to 41% cost-savings compared with a direct referral to coronary angiography.

Despite the higher direct costs of MPS with respect to conventional exercise ECG, MPS is more cost-effective because of its higher diagnostic accuracy and prognostic power, thus allowing a reduction in resources use for patients with a normal test result. Marwick et al. reported that a normal exercise ECG does not prevent additional diagnostic testing and causes an unexpected increase in the use of coronary angiography; on

“MPS may also lead to significant cost savings by limiting expensive therapeutic procedures”

extent to which the test selected as the first line approach induces the use of additional resources, i.e. the overall clinical strategy.

Strategies employing myocardial perfusion scintigraphy (MPS) have proven very cost-effective in several clinical scenarios. In patients with stable angina and

the contrary, patients with a normal MPS are infrequently referred for additional investigations.

MPS May Lead to Cost-Savings

In patients with overt CAD, MPS may also lead to significant cost savings by limiting expensive therapeutic procedures

to patients with high-risk scans who have the most to gain from an intervention.

In particular, the cost-effectiveness of MPS is particularly notable when we examine the results of this technique when applied to women, with a significant reduction in the number of normal coronary angiograms and an increase in the identification of those patients with multivessel coronary disease (from 23% to 42% of patients) as compared to a strategy including a direct referral to the cath lab as first line intervention strategy.

There are, however, studies reporting different conclusions. Hernandez and Vale, applying a probabilistic model analysis,

would more efficiently impact on the selection of the appropriate patient management, e.g. revascularisation versus medical treatment. In this context, strategies including stress imaging techniques demonstrated a better cost-effectiveness with respect to those including a direct referral to an invasive approach. It is worth noting that, in all class of pre-test likelihood of CAD, the two strategies resulted in a comparable event rate at follow-up.

The previous considerations also apply to the noninvasive assessment of coronary anatomy by multislice CT angiography (MSCT); in particular, when considering risk stratification as the major clinical decision point in both asymptomatic and

demonstrated higher sensitivity and equivalent specificity.

A Lower Rate of Adverse Events?

In addition, the negative predictive value of MPS for annualised hard event rate has been demonstrated to be significantly higher than that of stress echocardiography both in the general population and in patients with known CAD. This translates to a very low event rate in patients with negative MPS (<1%) when compared to patients with negative stress echocardiography (approximately 6%).

These rates of adverse events are too high to be fully effective in categorise a patient as “low risk”, particularly in patients with intermediate to high pre-test likelihood of CAD or known CAD, and a clinician is unlikely to be so confident on a negative test as to justify no additional testing.

However, the lower cost and the sufficiently high accuracy make echocardiography economically attractive for lower-risk diagnostic populations.

Conclusions

Widespread application of a combined clinical and stress imaging driven approach to patient management could result in substantial cost savings for the healthcare system, and in a survival benefit for those patients at risk of major cardiac events. In lower risk populations with suspected coronary disease stress echocardiography may be considered as the first line diagnostic test whereas, for intermediate-to-high-risk patients (including patients who are diabetic, with peripheral arterial disease, chronic kidney disease, or pre-surgical risk stratification), literature results support the use of the slightly more expensive nuclear cardiology imaging.

A full set of references for this article are available on request to the Managing Editor at edi.torial@cardiologymanagement.eu

“MPS is more cost-effective because of its higher diagnostic accuracy and prognostic power”

concluded that strategies that involve the use of SPECT seem to be optimal for low levels of prevalence of CAD, and in this setting they would reduce the number of invasive tests required.

For high levels of prevalence of CAD, the result seems to be the opposite; that is to say, strategies that involve the direct referral to angiography seem to be optimal. The conclusions of such an approach, however, seem to be limited only to the detection of the anatomical aspect (CAD) and do not consider the physiological aspect, i.e. the presence of ischaemic heart disease.

Appropriate Patient Selection Essential

In a more comprehensive clinical vision, both the detection of myocardial ischaemia and the associated risk stratification

symptomatic patients, appropriateness criteria for MSCT had recently obtained either uncertain or inappropriate scores.

MPS More Cost-Effective Than Stress ECG?

Most of the considerations of MPS results in a strategy that is more cost-effective than stress ECG or direct referral to the cath lab. Of course, these considerations might also be applicable to stress echocardiography, and the choice of the imaging stress modality (echocardiography or radionuclide imaging) often depends on which test is most available at a given institution and in local variation in accuracy.

However, in studies where head-to-head comparison between MPS and stress echocardiography were performed in the same population for vasodilators, dobutamine, and exercise stress tests, MPS

ESC CONGRESS 2010

28 AUGUST - 1 SEPTEMBER



EUROPEAN
SOCIETY OF
CARDIOLOGY®



STOCKHOLM

www.escardio.org

A MATTER OF COST OR OF EFFECTIVENESS?

Access to Medical Technology in Europe



AUTHORS

Prof. Giuseppe Boriani (above)
Dr. Alessandro Marziali
Dr. Mauro Biffi
Dr. Cristian Martignani
 Institute of Cardiology
 University of Bologna
 Bologna, Italy
 giuseppe.boriani@unibo.it

In this article, we will firstly present the case of two patients for whom, despite similar medical conditions, different therapies were advised, to highlight the inequality in access to medical technologies in Europe. Then, we will look at the matter of cost-effectiveness – are patients being differently treated in the same cases, due to financial pressures and despite thorough guidelines?

The case we present here not only shows that clinical use of electrical devices in Europe may not be homogeneous, but also highlights the fact that the relatively high cost of electrical devices may represent a factor that can condition, sometimes to a considerable extent, the decision to implant an electrical device “in the right patient, at the right time”.

Cases Highlight Differences in Therapy in Europe

A male patient, Luigi, aged 58, living in Italy, was diagnosed as being affected by dilated cardiomyopathy with depressed left ventricular ejection fraction (26%), in the absence of coronary artery disease. He

was followed for the last three years by a team of physicians working in a heart failure clinic, but in the last year his condition worsened (NYHA class III), with repeated hospitalisations for acute heart failure and recurrent atrial fibrillation.

Eight months ago, he underwent implantation of a device for cardiac resynchronisation therapy and in the following weeks his clinical condition improved markedly, with no further need for hospitalisation, no recurrences of atrial fibrillation and the possibility of reducing the use of diuretics. Quality of life and exercise capacity improved and he is now able to perform moderate physical activity without any problem.

Twenty days afterwards he was informed that his closest friend had died suddenly, during sleep, at the age of 61. As soon as he received this news, he had a sudden loss of consciousness, followed by delivery of a shock by the implanted device, with prompt resumption of consciousness. He was admitted to the emergency department and the physicians ruled out any coronary or major cardiovascular event; interrogation of the device

Luigi is in contact with his sister Anna, aged 62, who left Italy 25 years ago, moving to France. She too is affected by dilated cardiomyopathy (left ventricular ejection fraction 28%) and after a diagnostic work up (echocardiogram, exercise test, myocardial scintigraphy), was followed by her GP. She has been in stable condition for one year, but in the last six months, her condition worsened with shortness of breath requiring increasing dosages of diuretics, ace-inhibitors and carvedilol. The GP sent her for a series of consultations with the specific request of deciding about device therapy.

Unfortunately, the patient received conflicting advice: a first cardiologist suggested implanting a defibrillator, a second, after an echocardiogram showing ventricular dyssynchrony, advised implantation of a biventricular pacemaker (CRT-P device) and a third cardiologist told her that “The ideal device would be a device for biventricular pacing & defibrillation (CRT-D device) but the budget of our hospital is limited and since we are in October it is better to wait for the beginning of next year”. Anna was confused by the different suggestions coming from the

“The GP sent the patient for consultations to decide about device therapy. Unfortunately, she received conflicting advice”

revealed that loss of consciousness was due to high rate ventricular tachycardia at 230 bpm. The cardiologist said that the appropriate and prompt device activation had “saved his life”.

cardiologists who examined her and had difficulty understanding why there were discrepancies in decision-making; she was also worried about the potential risk of waiting before a decision.



Evidence-Based Guidelines Recommend Electrical Devices

The use, in clinical practice, of electrical devices to prevent sudden death by terminating ventricular tachyarrhythmias or to improve heart failure by resynchronising the left ventricle, is currently supported by strong evidence (Boriani et al., 2007). This evidence has been the basis for consensus guidelines (Vardas et al., 2007), which should constitute the reference for daily clinical practice.

Despite this, appropriate implementation of guidelines on the use of electrical devices in clinical practice is still an open issue and wide heterogeneity exists in implant rates. Implantable defibrillators (ICDs) and especially devices delivering both biventricular pacing for cardiac resynchronisation and defibrillator back-up (CRT-D devices) still have relatively high up-front costs and, in the absence of any economic analysis, their costs represent a limitation to widespread clinical use in the context of national or local financial constraints (Boriani et al., 2002).

Guidelines Do Not Govern Resource Usage

European guidelines, according to general policy, do not incorporate considerations on resource allocation and do not analyse the financial implications of device implementation, since all these evaluations are dependent on the specific national context where implementation has to be considered and they should thus be done at a regional/national level and not at a European level (Priori et al., 2003).

While in some countries this topic was directly addressed through national policy (this is the case of NICE), in others no precise rules were defined, leading to considerable variations in device therapy adoption, depending on local conditions (regional or hospital budgets, physicians' judgement, reimbursement, etc.). Extensive variations in ICD or CRT-D

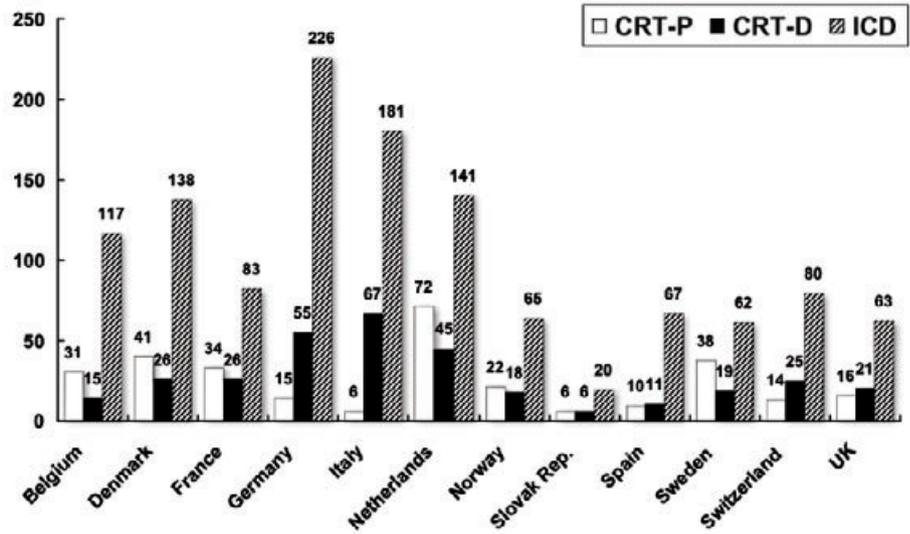


Fig. 1. Implant rates in different European countries for CRT-P, CRT-D and ICD devices, according to the Registry of the European Heart Rhythm Association (EHRA) (Ector and Vardas, 2007).

device implant rates exist among the various European countries, also with some differences between ICD and CRT-D or CRT-P implant rates (see figure 1) (Ector and Vardas, 2007).

Economic Tools May Help

Today, a series of tools for economic analysis (cost-effectiveness, cost utility and cost benefit analysis) may help in appropriate resource allocation at a national or regional level, according to a defined setting of healthcare priorities. Economic analyses are also available for ICD, CRT-D and CRT-P therapies (Boriani et al., 2002 and 2007) in order to better analyse the relationship between the clinical effectiveness attainable with these therapies and the cost of these devices.

In view of the benefit, confirmed by clinical trials, it appears that despite the high initial cost these devices may constitute a valuable investment for the healthcare systems in appropriate patients. Unfortunately, economic analyses do not at present seem to represent the basis for device therapy adoption in most European countries (Kearney et al. 2006, Boriani et al. 2007).

Health Technology Assessments Essential

A closer relationship between physicians, administrators and health economists, who often do not share the same language, and increased use of data coming from Health Technology Assessments and economic analyses, in the form of single studies or meta-analyses, may provide the basis for a more rational approach to the affordability of therapies, such as ICD and CRT-D, with a high initial financial burden but proven, evidence-based benefits.

This may be of value for ensuring fairness in access to these therapies, particularly for some less favoured subgroups of patients (females, the elderly, minority groups, etc.).

In addition, national and international registries focused on daily clinical practice may help in verifying and monitoring implementation of current guidelines in the real world. Such steps will constitute essential components of the complex pathways that, by moving from the evidence derived from clinical trials, will lead to the delivery of appropriate care to individual patients.

COST-EFFECTIVENESS OF IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS

Decreasing the Financial Burden



AUTHOR

Dr. Bharat K. Kantharia
Associate Professor of Medicine
Director
Clinical Cardiac Electrophysiology
Fellowship Training Programme

Also,
Director
Cardiac Electrophysiology Laboratories
Memorial Hermann Hospital
The University of Texas
Health Science Center
Houston, Texas, US
bkantharia@yahoo.com

The financial burden on society to treat and prevent sudden cardiac death (SCD) is enormous. ICDs effectively reduce SCD and are recommended for secondary and primary prevention of SCD from VT/VF. Unfortunately, ICDs are expensive and add to demands to healthcare budgets in even the most developed nations. In this article, we look at the cost-effectiveness of ICDs in different scenarios.

Cost-efficiency can be defined as achieving the maximal increment in benefit for a fixed amount of resources, and is typically expressed as an incremental cost-effective ratio (ICER), the ratio of changes in costs to the changes in effects. Cost-effectiveness analysis is a complex form of economic analysis that often includes “cost-effectiveness”, “cost-benefit” and “cost-utility” analyses. These analyses commonly measure effectiveness in Quality-Adjusted Life Years (QALYs).

Data on the Effectiveness of ICDs

Firstly, it is important to examine data on the effectiveness of ICDs. Among secondary prevention trials, “Antiarrhythmics Versus Implantable Defibrillators” (AVID) showed a greater survival rate with ICD than without - 89.3 % versus 82.3% at one year, 81.6 % versus 74.7 % at two years, and 75.4 % versus 64.1 % at three years. The other trials, Canadian Implantable Defibrillator Study (CIDS) and Cardiac Arrest Study Hamburg (CASH) also showed a reduction in mortality with ICDs. A meta-analysis of AVID, CIDS and CASH trials showed a 28% reduction in mortality with ICD. Among the primary prevention trials, the patient populations studied were:

- (a) Ischaemic cardiomyopathy, left ventricular ejection fraction (LVEF) < 35%, asymptomatic nonsustained VT, inducible and nonsuppressible VT for the Multicentre Automatic Defibrillator Implantation Trial (MADIT);
- (b) Ischaemic cardiomyopathy, LVEF < 40%, non-sustained VT, inducible VT for the Multicentre Unsustained Tachycardia Trial (MUSTT);
- (c) Ischaemic cardiomyopathy, LVEF < 30% for the MADIT-II trial, and
- (d) Ischaemic and non-ischaemic cardiomyopathy, LVEF < 35%, NYHA heart failure class II-III for the Sudden Cardiac Death in Heart Failure Trial (SCDHeFT).

MADIT, MUSTT, MADIT-II and SCDHeFT demonstrated a reduction in mortality with ICDs by 19% over two years, 31% over five years, 6% over two years, and

7% over five years, respectively. Among the patients with severe congestive heart failure (CHF) needing cardiac resynchronisation therapy (CRT), the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure Trial (COMPANION) trial showed lower (36%) relative reduction in all-cause mortality with CRT-D (ICD combined with CRT) when compared with optimised medical therapy.

Applying Cost-Effectiveness to ICDs

The MADIT and AVID trials reported ICERs of 27,000, and 66,677 dollars per year of life-saved during four and three year follow-up periods, respectively. As regards comparison with amiodarone, Owen et al showed the cost range per QALY varying from 37,300 to 74,400 dollars for mortality reduction by 20% and 40% respectively by ICD therapy in high-risk patients. Likewise, Caro et al demonstrated that compared to amiodarone, ICDs decreased deaths from 37.0% to 29.7% during five years at a net cost of 26,222 to 20,008 euros per patient, yielding a cost-benefit ratio of 0.17 for the population in the UK and 0.14 for the population in France. This translated into more than a five to one return on investment.

Prevention Cheaper than the Cure

Compared to amiodarone and other common cardiovascular drugs, the upfront total cost of ICDs is high. However, when compared on a ‘cost-per-day-of-use’, the cost of ICD therapy becomes low given the fact that ICDs keep the patients alive for a long period. The fact that four major countries in Europe spend annually, 6.14 billion euros for statins, 2.71 billion euros for ACE-inhibitors, 1.94 billion euros for



calcium channel blockers and 0.90 billion euros for betablockers, compared to 0.49 billion euros on ICDs, further highlights the cost-effectiveness of ICDs.

The risk of further cardiac arrest in the survivors of SCD remains high, with a mortality rate of over 45% at two years. Secondary prevention trials, AVID, CASH and CIDS have shown survival benefits with ICD therapy amounting to a 25% relative risk reduction for all-cause and a 50% relative risk reduction for arrhythmic

ICD reduced mortality for seven or more years. However, these analyses do not factor in issues such as inappropriate shocks, device-related complications such as infection needing antibiotic therapy or surgery or both, device malfunction needing component or generator change, etc. Repeated and prolonged hospitalisation for post-ICD care may thus in the long term cancel out the beneficial cost-effectiveness of ICD. Furthermore, cost-effective data analyses cannot be extrapolated from one country to the other.

38,389 dollars per life-year saved and 41,530 dollars QALY, respectively.

Of note, in the SCDHeFT trial, only single lead ICDs were implanted in outpatient settings, thus reducing the upfront cost of ICDs. In this trial, the cost-effective ratio was also sensitive to extrapolation beyond the empirical five-year trial data: 127,503 dollars per life-year-saved at five years, 88,657 dollars per life-year-saved at eight years, and 58,510 dollars per life-year-saved at 12 years. There was a significant interaction between ICD treatment and CHF functional class, such that despite incremental cost no incremental benefit was noted in class III.

“A further decline in the cost of these devices has recently occurred”

Cost-Effectiveness of ICDs in Elderly Patients

mortality to compared with antiarrhythmic drug therapy. The estimated cost-effectiveness ratios per life-year added were 66,677 and 139,000 dollars from the AVID and CIDS trials respectively.

For “primary” prevention, data from MADIT-II, SCDHeFT, and meta-analysis and review of several trials demonstrate that ICDs are cost-effective, and that the cost-effective ratio would remain below 100,000 dollars per QALY as long as the

Cost-Effectiveness of ICDs in CRT-D for CHF

Given the non-uniform design and nature of ICD trials in patients with CHF, it is difficult to form a unanimous conclusion on cost-effectiveness of ICDs including CRT-D for CHF. In SCDHeFT trial, ICDs compared to medical therapy alone, reduced all-cause mortality from 29% to 22% with lifetime cost-effectiveness and cost-utility ratios of

For practical purposes patients above age 65 years are considered elderly. In this patient population, there was lower or no statistically significant survival benefit from the ICDs as observed in MADIT-II and SCDHeFT trial respectively. In their analysis of healthcare costs and outcomes of ICDs for primary prevention of SCD in the elderly, Groeneveld et al showed significant reductions in mortality with ICD, but with a higher median hospital costs, by approximately 41,500 dollars, both in the first 30 days and at one year after initial hospitalisation, and with a higher outpatient and physician costs by approximately 1,800 dollars at 6 months. These additional healthcare costs of ICD implantation were deemed comparable to published cost-effectiveness models that have projected ICDs to be cost-effective.

The Scope of Sudden Cardiac Death

The worldwide incidence of SCD is very high. In the US the estimated annual incidence is approximately 300,000. Similar population-incidence of 1/1,000 per year has been observed in Europe and Japan. Given such a scope of SCD, the cost-effectiveness of ICDs should not just be addressed for prevention of SCD in ischaemic and dilated cardiomyopathies substrates but also for specific conditions, for example, long QT syndromes (LQTS), Brugada syndrome, hypertrophic cardiomyopathy (HCM), for which ICDs are recommended.

Since the early reports in 1980s by Dr. Mirowski, the inventor of implantable cardioverter defibrillator (ICD), and his colleagues, only ICDs have shown to effectively reduce SCD and thus are recommended for secondary and primary prevention of SCD from VT/VF. Unfortunately, given their high cost, ICDs have also added financial burden and posed challenges on the national healthcare budgets even in the most developed nations. It is, therefore, justifiable to question and fully assess the cost-effectiveness of ICDs.

Conclusion

Many landmark clinical studies have shown ICD therapy to be highly effective in the treatment of SCD. Economic analyses also support the cost-effectiveness of ICDs. Additionally, a further decline in the cost of the devices has occurred recently. One would therefore hope that on balance the healthcare budget of many nations would allow and promote ICD therapy for prevention of SCD for high-risk patients as a standard therapy.

THE UK CENTRE FOR EVIDENCE-BASED PURCHASING (CEP)

Cost-Effective Healthcare Technology Assessments



AUTHORS

Helen Cole (above, left)
Business Development Manager

Lizzy Bower
Health Economist

Centre for Evidence-based Purchasing
London, UK
www.pasa.nhs.uk/cep
cep@pasa.nhs.uk

Our central role is to provide assessments on clinical utility and cost-effectiveness, supporting the delivery of DH and NHS policies and priorities. Our multi-faceted work programme is planned through extensive consultation with national organisations and professional bodies, ensuring best use of our resources and an impact on procurement.

CEP commissions projects from a range of multidisciplinary expert groups, many in NHS and academic institutions in the UK. Our reports, summarised here, and freely available to download from the CEP website, include:

- Advances in Cardiac Imaging
- Surgical Intervention and Post-Intervention Care
- Vacuum Assisted Closure® (VAC) Therapy
- Implantable Cardiac Devices
- Centralised Telehealth Services
- Ultrafiltration Therapy & Heart Failure

The Centre for Evidence-based Purchasing (CEP) was created within the UK National Health Service (NHS) Purchasing and Supply Agency (PASA). Funded by the UK Department of Health (DH) it delivers free, independent and impartial evidence to healthcare providers to underpin purchasing decisions and to drive adoption of useful, innovative healthcare technologies in the NHS. This article will focus on CEP projects relating to innovations in cardiology management and report on how we contribute to the evidence-base for demonstrating cost-effectiveness in procurement.

Advances in Cardiac Imaging

CEP published an evidence review of multi-channel radiofrequency (RF) and parallel imaging technologies for magnetic resonance imaging (MRI) scanners. Multi-channel RF and parallel imaging technologies are hardware and software implementations respectively, aimed at improving the coverage, signal, resolution, and speed of MR examinations. CEP reached a verdict that these advances have significant potential for delivery of cardiovascular imaging services.

Surgical Intervention and Post-Intervention Care

We also published an evidence review of oesophageal doppler monitoring (ODM) in patients undergoing high-risk surgery and in critically ill patients. For such patients, cardiac output monitoring may be used to guide fluid replacement and drug treatment, helping to maintain adequate blood supplies to the tissues. ODM may therefore have the potential to reduce mortality, complication rates, length of stay in critical care facilities and overall hospital stay.

“Faster scanning could increase patient throughput and improve their comfort”

Faster scanning could increase patient throughput, as well as dramatically improve patient comfort during scans. The ability to achieve higher resolution without increased examination times is particularly valuable in most MRI cardiovascular examinations.

Studies Question Use of Pulmonary Artery Catheter

Recent studies indicate that the pulmonary artery catheter, traditionally used to monitor cardiac output, may not be beneficial in these groups of patients.



Patients undergoing surgery or critical care may receive only non-invasive assessment of markers such as heart rate, systolic blood pressure, and urinary output (conventional clinical assessment), with or without catheter-based measurement of central venous pressure (CVP); the anaesthetist generally decides which patients also need monitoring of their cardiac output.

ODM is already widely used in the NHS: one such type of monitor is used in around 25,000 patients each year; but considering the large number of potential patients, its use seems to be relatively infrequent. CEP reached a verdict that ODM offers significant potential for these two categories of clinical use, including the potential cost benefits of

Implantable Cardiac Devices

An evidence review and economic report on implantable cardiac devices with remote monitoring facilities is in preparation. Patients with pacemakers, implantable cardioverter defibrillators (ICDs) and other implanted cardiac devices require regular monitoring to ensure that the implanted device is working optimally and still suits the cardiac disease for the individual patient. This monitoring is usually undertaken at hospitals with specialised equipment and highly experienced staff.

Additional follow-up visits may be required to investigate symptoms that may or may not relate to either the implanted device or patients' cardiac con-

dition. CEP completed an extensive project reviewing the evidence and developing a cost analysis for ultrafiltration (UF) therapy for the removal of excess fluid in patients with heart failure, with a subsequent evaluation of the performance of one commercial product, the CHF Solutions Aquadex Flexflow. Ultrafiltration is a non-pharmacological therapy for removing excess water and salts from the bloodstream.

Ultrafiltration Therapy & Heart Failure

CEP reached a verdict based on the evidence reviewed and evaluation of the Aquadex Flexflow that UF offers significant potential to become a routine therapy for excess fluid removal in patients with congestive heart failure. However, further work is needed to establish the patient groups who would benefit most, the optimal rates of fluid removal, the conditions for termination of therapy, and the cost savings associated with long-term quality of life benefits.

The cost analysis modelled the clinical pathway associated with the use of ultrafiltration compared with diuretics, for patients with chronic heart failure in an inpatient setting. Consumables were identified as the key driver for the higher treatment cost of ultrafiltration; however, its use in a day case setting significantly reduced treatment costs. The analysis was limited by the data available and an interactive model is available on the CEP website to allow the input of individual data to encourage further data collection at local level to support local purchasing decisions.

run a local EU tender exercise, thereby saving costs and staff time. The provision of a telehealth service allows patients to remain under observation at home, improving their lifestyle and wellbeing, whilst minimising unnecessary hospital admissions and enabling cost and efficiency savings to the NHS as a result.

“Home monitoring could allow many of these visits to take place remotely”

reduced hospital stay, with the report presenting these conclusions in more detail.

Vacuum Assisted Closure® (VAC) Therapy

CEP has published an evidence review of Vacuum Assisted Closure® (VAC) therapy, a device that applies topical negative pressure to accelerate wound healing of complex and non-healing wounds, such as diabetic ulcers or infected sternal wounds. VAC therapy uses a combination of vacuum suction and specialised dressings to facilitate wound drainage and influence the growth of surface tissues.

The majority of evidence does indicate a benefit in comparison with 'standard wound care' e.g. saline moist gauze, however the benefit is less clear when compared with 'advanced wound care' (e.g. hydrocolloids, alginates), in the treatment of chronic and acute wounds. CEP is currently working on a project to review the evidence for these advanced wound care dressings.

dition. Home monitoring could allow many of these follow-up visits to be carried out remotely, without the patient having to attend hospital. The economic evaluation compares the costs and outcomes associated with the treatment pathway for remote monitoring to the current monitoring pathway.

Centralised Telehealth Services

A national framework agreement launched by the NHS Purchasing and Supply Agency, covers telehealth equipment, installation, maintenance, monitoring and response services. Services relating to cardiology management in the home were evaluated by CEP and include remote monitoring of blood pressure, blood glucose and cardiac arrhythmia, plus integrated health monitors and medication reminder systems.

This 'once-only' EU tendering exercise allows commissioners to access telehealth products and services directly from the framework, without the requirement to

Full copies of all CEP reports are free to download from: www.pasa.nhs.uk/cep



**WORLD HEART
FEDERATION®**

**World Congress of Cardiology
Scientific Sessions 2010**

Featuring the 3rd International Conference on Women,
Heart Disease and Stroke

16-19 June 2010 | **Beijing, China**

世界心脏病学大会 2010

暨第三届国际妇女心脏病和脑卒中学术会议,
中华医学会第十二次全国心血管病学术会议

2010年6月16日-19日 | **中国 北京**



www.worldcardiocongress.org





CALCULATING YOUR COSTS

Principals of Economic Evaluations



AUTHOR

Dr. Hema Mistry
Research Fellow in Health Economics
Health Economics Research Group
Brunel University
Uxbridge
Middlesex, UK
hema.mistry@brunel.ac.uk

Clinical trials measure healthcare outcomes to determine the efficacy of healthcare interventions. Economic evaluations provide valuable information to help decision-makers allocate scarce resources more efficiently and to see whether the intervention represents good value for money. Two methods can be used to determine cost-effectiveness: an economic evaluation alongside a clinical trial, which estimates the costs and outcomes during the trial period; and a modelling approach extrapolating costs beyond the trial duration. This article will describe what an economic evaluation is and how to conduct one.

What is Economic Evaluation?

Economic evaluation is concerned with minimising opportunity costs (the value of the next best alternative foregone as a result of the decision made) so that the best use is made of scarce resources. Therefore, we have to make choices, by comparing costs and outcomes of alternative treatments. The basic tasks of any economic evaluation are to identify, measure, value and compare the costs and consequences of the alternatives being

considered. There are five types of economic evaluation (see table 1) and each measures costs in monetary units. However, they differ in the way consequences are included.

At the start of any economic evaluation, you need to specify the following:

- Research question (i.e. the cost-effectiveness of cardiac interventions);
- Study perspective (i.e. healthcare);
- Time frame of analysis (i.e. lifetime of patients);
- Analytical approach (i.e. decision model);
- Options for comparison (i.e. drug A compared with drug B), and
- Approach to costs and outcomes (see fig. 1, page 19).

Each of these issues will determine the scope of costs and outcomes; which are included, how they are measured and valued, and how they are reported and interpreted.

Determine Which Costs are Relevant

The study perspective will determine which costs are considered relevant for the evaluation. For any economic evaluation, you need to identify categories of key resource use (i.e. inpatient stays) and then measure them in their physical units (i.e.

number of bed days). There are various sources that we can use to measure resource use, such as randomised trials, clinical databases, medical records, patient questionnaires and literature. Ideally for any economic evaluation, resources should be valued by their opportunity cost. However, this is not always practical and market prices are usually used to value resources in units of local currency (i.e. average cost per bed day).

Valuing Health Outcomes

The outcomes used in economic evaluations depend on the research question and the type of evaluation being conducted (see table 1). These include:

- Clinical measures which use natural units (i.e. number of cardiac cases detected);
- Disease specific instruments (i.e. hospital anxiety and depression scale);
- Mortality measures which look at life years gained;
- Generic measures which use instruments to measure overall health-related quality of life (HRQoL), etc.);
- Utility measures, a special kind of generic measure that give an indication of value placed upon the HRQoL (i.e. EQ-5D), and
- Monetary measures which value benefits in terms of currency.

Table 1. Different types of economic evaluations

Type of analysis	Measurement of costs	Measurement of outcomes
Cost-minimisation (CMA)	Monetary	External evidence of equivalence
Cost-consequences (CCA)	Monetary	Array or profile of different measures
Cost-effectiveness (CEA)	Monetary	Single, natural or clinical units
Cost-utility (CUA)	Monetary	Quality-adjusted life years
Cost-benefit (CBA)	Monetary	Monetary valuation

There are two main approaches to valuing health outcomes: monetary and non-monetary. Non-monetary valuations include scales that ask participants to rank health outcomes or place outcomes on a scale such as the visual analogue scale. Also, the standard gamble approach is based on the axioms of expected utility theory and asks respondents to make choices that weigh improvements in health against mortality risks. Finally there is the time trade-off approach, a method for valuing health states that asks respondents to make hypothetical choices that weigh improvements in health against reduced longevity. Monetary valuations include revealed preferences where individuals assess the benefits in accordance with their preferences; and stated preferences are where valuations are derived from surveys such as willingness-to-pay studies.

The Role of “Modelling” in Evaluation

Modelling is used in economic evaluations when trial data does not exist, and can be used to extrapolate existing data beyond a certain time period. Decision analytical modelling represents the various clinical pathways for alternative treatments and quantifies the probability of a patient following each pathway. For each pathway, the range of possible costs and health-related outcomes can be calculated.

The aim of the decision model is to calculate the expected (i.e. the mean) costs and outcomes of the alternatives together with the uncertainty in those estimates. Decision modelling looks at a process in which a fixed sequence of events leads to an outcome, but does not take into account the time dimension. On the other hand, Markov modelling is useful in analysing the evolution of health states over time for a particular illness.

Handling Uncertainty

Every economic evaluation will contain some degree of uncertainty: parameter

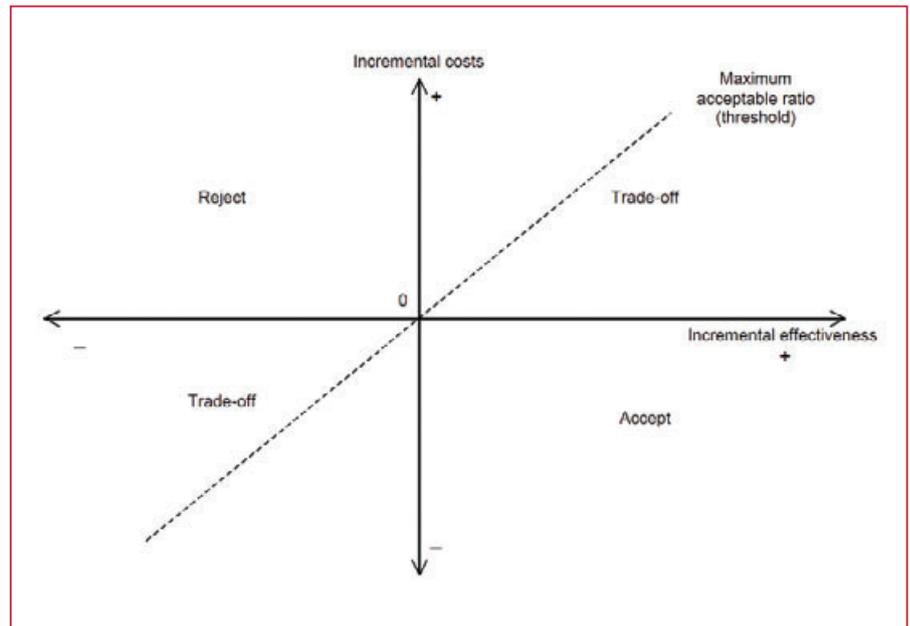


Fig. 1. Cost-effectiveness plane

uncertainty is where you are unsure about the true numerical values of the parameters used as inputs; and model uncertainty is where you are unsure about the correct method for combining parameters, and/or the analysis which may have been completed. There are several methods for handling uncertainty, the simplest being a one-way sensitivity analysis, where each parameter is varied one at a time in order to investigate the impact on study results, through to more sophisticated methods such as probabilistic sensitivity analysis where one can incorporate the uncertainty of all the parameters in the model simultaneously.

Presentation and Interpretation of Results

If the study period in question is greater than a year, then costs and outcomes should be discounted. Discounting allows future costs to be converted into present values, thereby allowing comparisons between costs and outcomes that occur at different times. The incremental cost-effectiveness ratio (ICER) is the difference in costs between one intervention and an alternative, divided by the difference in outcomes. This ratio represents the extra amount one would pay for an additional unit of health

outcome. Cost-effectiveness planes are used to present results (see fig. 1).

In this figure, the x axis represents the differences in effects for two interventions and the y axis represents the difference in costs for the two interventions. The slope of the line is known as the maximum acceptable ICER. If the costs and benefits for the intervention fall below that threshold you would probably choose to adopt it. The uncertainty in economic evaluations are presented as cost-effectiveness acceptability curves (CEACs) which are used to indicate the probability that an intervention is more cost-effective than the alternative for a range of potential maximum amounts (ceiling ratio) that a decision-maker is willing to pay.

Conclusions

Economic evaluations are increasingly being used to inform decision-making about which healthcare interventions should be used/adopted. For any economic evaluation, the following need to be considered: the research question, the study perspective, the time horizon, the analytical approach, the options for comparison, the approach to costs and outcomes and dealing with uncertainty.

Lisbon, Portugal
September 19-23
CIRSE 2009

**INNOVATION
EDUCATION
INTERVENTION**

CIRSE 2009, Europe's most comprehensive forum for minimally invasive image-guided therapy, will offer more than 100 hours of educational and scientific presentations streamlined around six major topics, hands-on workshops, foundation courses, learning centres, industry symposia, an all electronic poster exhibition and the biggest CIRSE exhibition ever.

www.cirse.org

MAIN TOPICS

- **Vascular Interventions**
- **Transcatheter Embolization**
- **Non-Vascular Interventions**
- **Interventional Oncology**
- **Clinical Practice**
- **Imaging**

CARDIOLOGISTS INCREASINGLY UTILISING PORTABLE ULTRASOUND

Trend Shows Technological Advances Fuelling Growth



AUTHOR

Diane Wilkinson
Market Analyst
Medical Electronics Research Group
InMedica
IMS Research
Wellingborough, UK
diane.wilkinson@in-medica.com

The ultrasound imaging equipment market is currently seeing a clear trend towards miniaturisation. The dramatic increase in the use of hand-held and portable ultrasound (defined by InMedica as compact ultrasound), has driven additional growth for ultrasound in markets such as cardiology.

Developments in the ultrasound imaging market today focus on improvements in diagnostic performance and workflow

enhancements. The trend to portability further aids improvements in point-of-care services and ultimately, patient care. With the ultimate goal of increasing the efficiency and productivity by which hospitals and clinics operate, these enhancements are necessary to ensure increased patient volume and throughput, and consequently, the survival of many hospitals and clinics globally. This holds particular relevance in the current environment where the cost of healthcare is vastly outpacing government spending and reimbursement.

Cardiologists Increase Uptake of Portable Ultrasound

The trend to miniaturisation is affecting the use of ultrasound by cardiologists. A recent survey by InMedica on the use of ultrasound in western European hospitals and imaging centres has highlighted that cardiologists expect to be using much more mobile ultrasound in the near future, with emerging applications for ultrasound in cardiology including emergency room, critical care and bed-side exams.

Cardiologists from across Europe were recruited in this research, to help equipment manufacturers improve their product development and overall service to customers. Working in partnership with a number of leading equipment manufacturers, InMedica designed a questionnaire to gather direct feedback from cardiologists on the equipment they are using, the examinations they are performing, ways in which their systems could be improved and how their work is changing. The results of the survey are presented by InMedica in the report, “European Customer Insights – Ultrasound in Cardiology”.

Survey Results

Table 1 presents the types of ultrasound systems being used by the surveyed cardiologists. While 100% of respondents were using cart-based ultrasound in cardiology, InMedica found that 46% of respondents were also using a portable ultrasound system to complement their traditional cart-based system. Furthermore, 73% of respondents expected to be using hand-held ultrasound within the next five years.

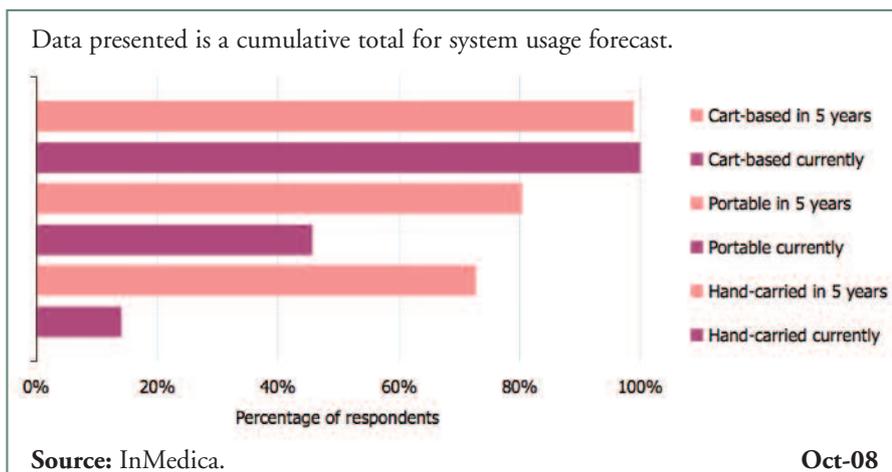
For future use of hand-carried and portable ultrasound systems in cardiology, 85% of respondents answered that their role would be complementary to cart-based systems. Moreover, 6% thought cart-based systems would be fully replaced by hand-carried and portable systems. Only 9% of respondents thought that hand-carried systems played no future role for the use of ultrasound in cardiology.

Workflow Benefits

In relation to workflow, the greatest numbers of responses (25% of cardiologists) were in relation to the positive use of hand-

continued on page 25

Table 1. What types of ultrasound systems are being used by cardiologists?



MULTIDISCIPLINARY MANAGEMENT OF CARDIOVASCULAR RISK

Using a Nurse-Coordinated Family-Based Approach



AUTHOR

Catriona Jennings
 Cardiovascular Specialist Research Nurse
 Department of Cardiovascular Medicine
 National Heart and Lung Institute
 Imperial College London
 Charing Cross Hospital
 London, UK
 c.jennings@imperial.ac.uk

EUROACTION, a demonstration project in preventive cardiology, was launched in 2003 in eight European countries (Denmark, France, Italy, the Netherlands, Poland, Spain, Sweden and the UK). Using a matched paired cluster randomised controlled trial study design (see Fig. 1), it aimed to show that nurse-led care could facilitate the implementation of European and national guidelines for CVD prevention in everyday clinical practice. It was set up in 12 district general hospitals and 12 general practices, half of which were randomly assigned to receive the EUROACTION preventive cardiology programme and half which were monitored for the usual care they provided.

In hospitals, the study prospectively identified all consecutive patients presenting for the first time with acute coronary disease (acute myocardial infarction or unstable angina) or exertional angina as inpatients or outpatients in each centre. In general practice, patients were opportunistically identified by their general practitioners at high total risk of developing cardiovascular disease (CVD) as calculated using the

European heartscore risk estimation tool (\geq 5% risk of dying from CVD over the next ten years), or currently under treatment with blood pressure and/or lipid lowering therapies and/or diagnosed with diabetes.

The primary one year endpoints were family-based lifestyle changes (not smoking, adoption of a cardio-protective diet, increased physical activity), reduced body weight and in particular central obesity, management of blood pressure, lipids, and blood glucose concentrations to target, and prescription of cardio-protective drugs. Analysis was by intention to treat.

Cardiovascular Specialist Nurses as Managers

Cardiovascular specialist nurses were employed to manage dedicated multidisciplinary teams. Nurses were responsible for the delivery of the smoking cessation inter-

vention, dieticians for dietary and weight management intervention, and physiotherapists for physical activity intervention. Cardiologists were available to advise on symptom and risk factor management with medications. The nurse in general practice was trained to deliver a comprehensive lifestyle and risk factor programme with the support of physicians.

The hospital team worked together, sharing the same office space to manage patients and their family members attending the programme. The programme had certain key elements:

- Proactive identification of all eligible patients;
- Invitation to both patients and their partners (and first degree relatives where appropriate) to join the programme;
- A comprehensive multidisciplinary assessment of both the patient and their partner of all aspects of lifestyle,

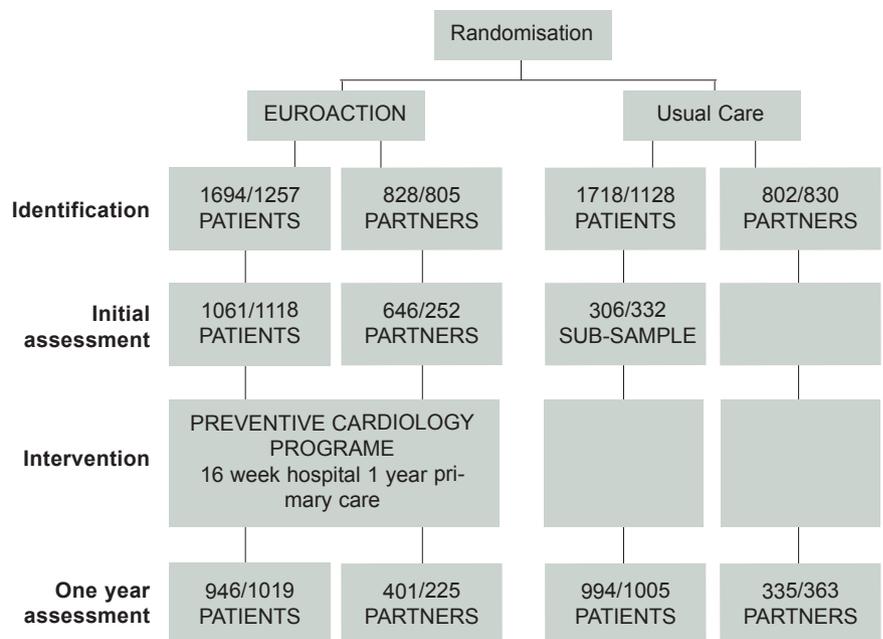


Fig. 1. Design of the EUROACTION matched paired cluster randomised controlled trial

- risk factors, cardio-protective medications, health-related quality of life, health beliefs, illness and risk perception;
- Goal setting in negotiation with both patient and partner;
 - A professional lifestyle management programme for smoking cessation, healthy eating, promoting physical activity and achieving a healthy weight and shape;
 - Protocol management of blood pressure, lipids and glucose by the nurse working with physicians to achieve treatment targets;
 - Prescription and up-titration of cardio-protective medications by cardiologist/general practitioner;
 - Weekly attendance of the programme over 16 weeks;
 - Regular multidisciplinary meetings of the core team with the cardiologist/-general practitioner to discuss progress and update the plan of care, recorded in the medical notes to be addressed at the next programme attendance;
 - Hospital team/general practice nurse to follow up each family when they attend the programme to agree lifestyle plan and to give prescriptions;
 - Weekly supervised exercise sessions, and
 - Group health promotion workshops.

Why Nurses to Coordinate?

Each programme employed a full-time specialist nurse to coordinate the multidisciplinary team and to facilitate programme delivery. Nurses were chosen for this role for the following reasons:

- Nurse training and bachelor degree programmes incorporate the medical, biological, social and behavioural sciences as well as health psychology. In addition, they have the opportunity to learn counselling and teaching skills.
- Nurses are accustomed to working closely with the medical profession and to implementing medical decisions about care.
- They are trained to understand symptoms and monitor patients' signs, e.g. blood pressure.
- They can cope with patients' emotional problems (e.g. fear or denial).
- They are trained to safely administer medicines, are familiar with medica-

Table 1. Lifestyle Results

	Hospital			General Practice		
	I n=946 (%)	UC n=994 (%)	% change (95% CI)	I n=1019 (%)	UC n=1005 (%)	% change (95% CI)
n= attending at 1 year						
Not smoking	58†	47†	10.4 (-0.3 to 21.2)	74	72	0.8 (-13.1 to 14.7)
Achieving saturated fat goal	55*	40	17.3 (6.4 to 28.2)	Not measured		
Achieving goal for fruit and veg	72*	35	37.3 (18.1 to 56.5)	78*	39	39.7 (18.1 to 61.3)
Achieving oily fish goal	16*	8	8.9 (0.3 to 17.5)	11	6	6.7 (-4.1 to 17.6)
Achieving physical activity goal	54*	20	35.6 (20.0 to 51.3)	50*	22	29.4 (10.7 to 48.0)

* $p < 0.05$

† of coronary patients who were smokers

I = intervention

UC = usual care

- tions, doses, potential interactions, etc.
- They follow professional recommendations and protocols well.
 - Training also includes management theory. In their professional role, nurses have to coordinate nursing teams on the hospital ward and other disciplines, e.g. physiotherapists, pharmacists, etc.

However, nurses must access adequate training for these extended roles, know their capabilities and accept their limitations and understand when it is appropriate to refer to other disciplines or seek the advice of doctors.

What did the Approach Achieve?

1,589 and 1,499 patients with CHD in the hospital study and 1,189 and 1,128 at high risk of developing CVD were recruited to intervention and usual care centres respectively. The analyses were based on intention to treat using random effects modelling so as to take account of a cluster randomised controlled design. Tables 1 and 2 (see above and page 46, respectively) show the principal results reported at one year.

In the physical activity results, half or more of both coronary and high-risk patients in the intervention groups reported achieving

the physical activity goal of at least 30 minutes of moderate intensity activity on at least five days of the week compared to less than a quarter in usual care. Also encouraging were the dietary results with significantly more coronary patients in the intervention group compared to usual care achieving the low saturated fat target, the high consumption of fruit and vegetable target and the oily fish target.

In the EUROACTION study, most coronary patients who smoked at the time of their event had stopped by the time of the initial assessment. Therefore the challenge for nurses was to prevent relapse in this group in the programme. 58% in the intervention group compared to 47% in the usual care group were not smoking (validated by breath carbon monoxide) at one year. Although of borderline statistical significance ($p=0.06$), this absolute difference of 10% less smoking relapse is clinically important. Amongst high-risk individuals in general practice, despite more quit attempts being made in the intervention group, the proportions not smoking at one year were no different from usual care. This was probably due to a very low use of pharma therapies to aid smoking cessation.

continued on page 46

DRIVING QUALITY STANDARDS IN PAEDIATRIC ECHOCARDIOGRAPHY

How to Cultivate Leadership and Teamwork



AUTHORS

Dr. Mark Lewin (above left)
Joel Lester, RDCS
 Paediatric Echocardiography Laboratory
 Seattle Children's Hospital
 Heart Center
 Seattle, US
 mark.lewin@seattlechildrens.org

Echocardiographic imaging has evolved into the key diagnostic modality in paediatric cardiac care. Its role has expanded beyond that of initial diagnosis; intracardiac echo is now used during interventional cases in the cardiac catheterisation laboratory, transthoracic echo is the pre- and post-operative modality, and transesophageal echo is utilised in the operating room (see table 1). In this article, we elaborate the new, adapted management strategies that the echo lab must adopt to achieve effective use of these diverse imaging tools.

Role of the Paediatric Echo Laboratory Manager

It is vital that the echo lab manager have an accurate understanding of the field of echocardiography. A manager who has experience as a sonographer can best understand the needs and challenges of the bedside sonographer. It is critical that the manager is engaged in day-to-day operations; this will yield a laboratory where decisions are made which correlate with effective operations. This will also increase the likelihood of a healthy rela-

tionship between manager and sonographer, thus reducing turnover and enhancing job satisfaction. Finding skilled sonographers can be challenging enough, but retaining them in a healthy work environment is yet another matter.

Creating a culture in which teamwork is a theme is crucial in optimising employee engagement. Appointing an echo laboratory manager focused on directing the sonographer's energies towards the desired result by allowing the employees to problem-solve and divide responsibilities among themselves will empower them to work as team. The manager can then step back and develop novel methods of supporting the staff. Our hospital has gone to great lengths to ensure that management has the tools and resources to create a healthy network of team-building. For example, we arranged hour-long workshops over the lunch hour on two consecutive days to create an "Echo Lab Purpose Statement", as follows:

Echo Lab Purpose Statement

"As an integral part of the heart centre team, we strive to provide our patients with high-quality echocardiograms in a compassionate, family-centred environment."

As mentioned, the echo laboratory spans most aspects of paediatric cardiac practice. We have assigned sonographers to develop special skills in a specific area where they have expressed interest. Again, half the battle is to ensure employee satisfaction and encourage their growth. We direct sonographers to specialise in a particular aspect of paediatric cardiology including transplant evaluation, transesophageal imaging in the operating room, cardiac imaging of the foetus, and dobutamine stress echocardiography.

Other guidelines set by our institution oblige us to demonstrate "ARTful" behaviors (Accountability, Respect and Teamwork). This is included in our work content description to emphasise this as a job requirement and a part of our yearly evaluation. Each new employee is told about these expectations from their first day of employment. Each month the hospital recognises the ARTist of the Month – one who demonstrates the highest standards as judged by their peers – an excellent way to reward those who can set an example for the rest of us.

Education in the Paediatric Echo Laboratory

Our leadership team uses diverse methods to educate staff, measure quality, and provide feedback. The echo laboratory manager and physician leader work together to develop internal education initiatives for the sonographers, such as a standardised lecture series occurring at a time of the day when as many staff as possible can attend.

These lectures are attended by sonographers, cardiology trainees and echo lab physicians.

Weekly case conferences discuss complex as well as straightforward cases. We encourage our paediatric sonographers to

Table 1. Study Types in the Paediatric Echo Laboratory

Transthoracic echo (TTE)
Transesophageal echo (TEE)
Dobutamine Stress echo (DSE)
Exercise Stress echo
Foetal echo
Intracardiac echo (ICE)

Table 2. *Equipment and Personnel Metrics in the Paediatric Echo Lab*

Echo machines	1 per 1,000 studies
Echo machine upgrades	1 per year
Sonographer volumes	6 - 7 studies per day (avg.)
Echo physician interpretation volumes	35 per day (max)
Digital storage (SAN)	18 month short-term (min) - long term archiving thereafter
Study reporting	Paediatric-specific templates

attend these conferences. We also organise one-on-one sessions between an individual sonographer and an echo laboratory physician so that each sonographer's individualised needs can be determined. We provide these types of one-on-one interaction informally whenever a specific patient-focused question arises, but also in a more standardised setting for each of our 12 sonographers numerous times throughout the year.

As part of our sonographer's RDCS recertification, CME credits are required. Our goal is to allow each sonographer to attend a national meeting every other year. This allows for CME credit accrual, and also provides a mechanism for the sonographers to stay up-to-date via interactions with nationally-recognised experts in the echocardiographic assessment of paediatric heart disease.

Quality Assurance Models

Quality assurance in the echo laboratory occurs in a variety of ways. There is the internal group review of studies for imaging accuracy as well as interpretation of the data via correlation of images to informa-

tion found in the study report, and quarterly assignment of studies by the echo laboratory manager such that sonographers are responsible for individually (but anonymously) critiquing each others work.

In addition, the members of the echo laboratory participate in more global heart centre-wide quality initiatives. These morbidity and mortality conferences are often meant to address system issues, and to this end correlation of different imaging modalities often occurs (for example comparing data obtained and conclusions developed from echo studies versus cardiac catheterisation, cardiac magnetic resonance, and cardiac computerised tomography). Our goal is to ensure the highest level of accuracy and quality in an educational setting which is nurturing and respectful of the sonographer and echo lab physician.

Laboratory Accreditation

The Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) serves as the accreditation mechanism for both general and paediatric echo laboratories. Accreditation requires submission of case-

based studies, data regarding the quality assurance mechanisms for the particular laboratory, data regarding standardisation of study methodology, study volumes for interpreting physician and performing sonographer, information regarding study scheduling and ordering, and criteria regarding equipment maintenance.

After initial accreditation, renewal is required every three years. While there are only a handful of insurers who have as yet adopted echocardiography reimbursement directives (including ICAEL certification), it is very likely that this will increase. This will apply not only to the technical aspect of billing, but also to reimbursement for professional fees.

Summary

The paediatric echo laboratory is unique in regards to staff-patient interactions and the skills to make these interactions successful, the methodologies by which studies are performed, the training of the sonographer performing the paediatric echocardiogram, laboratory accreditation, and the methods of study reporting. This results in the need to organise and manage the paediatric echo laboratory differently than the general laboratory.

The interaction between the laboratory, the members of the cardiac team, and the other paediatric providers results in the echo laboratory serving in many ways as the focal point of paediatric cardiac care. Without effective strategies in place to develop sustainable standards of quality, outcomes associated with paediatric cardiac care would most certainly be compromised.

continued from page 21

carried and portable systems in emergency, critically ill and bedside examinations. 21% of respondents considered these systems to have a "strongly positive" impact in cardiology, relating to the increased use and importance of hand-carried and portable systems in ad-hoc and routine exams. Conversely however, 19% of respondents considered that these systems would have little or no impact on work-

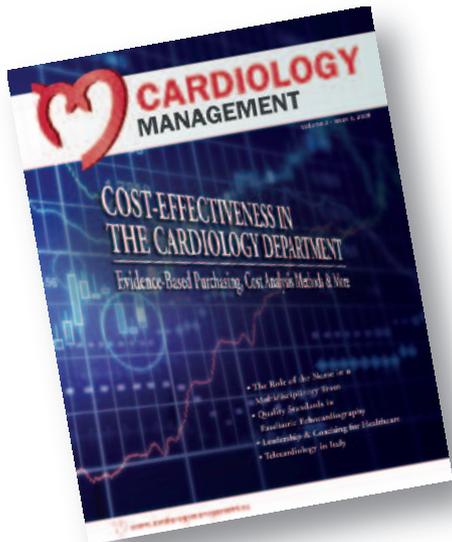
flow in relation to cardiology. The survey also showed that cardiologists expect their work to become more mobile in future, with bedside examinations becoming common practice. Outpatient examinations were also expected to increase in regularity. By taking ultrasound to the patient, a reduction in waiting times can be achieved as all scans will not have to be referred to overstretched imaging departments.

Quality of Care to Rise

Screening and minor scans can also be performed using portable equipment, often by non-imaging specialists, only referring patients to the imaging departments for in-depth scans for serious conditions. The increased use of ultrasound, particularly in new applications, will raise the overall quality of care.

Free Subscription Form

For Members of ESC



Title & First Name: _____

Surname: _____

Job Title: _____

Institution: _____

Address: _____

Postcode & City: _____

Country: _____

Telephone: _____

Email: _____

ESC Membership Number: _____

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, Echocardiography, Cardiac CT)
Cardiac Surgery/ Cardiovascular Surgery
Paediatric Cardiology
Other (please specify)
- 1b. I am Chief of my Department
Yes
No

Non-physician professionals (respond below)

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

Executive

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

Other

Medical Physicist
Academic
Chief Technologist
Manufacturer
Business Consultant
Distributor / Dealer

All respondents reply to the questions below

2. In what type of facility do you work? (check only one)
- Private clinic
Hospital (check number of beds)
More than 500 beds
400-499 beds
300-399 beds

3. How many beds is your ward equipped with?
- More than 30 beds
15 - 30 beds
Less than 15 beds
4. With what technologies or disciplines do you work? (check all that apply)
- Echography
Interventional Cardiology
Angiography
Cardiac CT
Cardiac MRI
Cardiology PACS
5. What is your role in purchasing
- Final say
Influence
No role

FAX BACK TO +32 2 286 8508

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, and
- 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

THE EFFECTIVENESS OF NURSE-LED CLINICS

Increasing Patient Satisfaction



AUTHORS

Tamara Page (above left)
Tiffany Conroy
 Royal Adelaide Hospital and Discipline
 of Nursing,
 University of Adelaide
 Adelaide, Australia
 tammy.page@health.sa.gov.au

Coronary heart disease (CHD) and the impact it has on society will continue to increase, as the average age of the population rises. Advances in prevention and treatment have increased survival rates in patients with CHD. Continuing interventions for patients already diagnosed with CHD impacts on further coronary events they may experience and ultimately impacts on their mortality. Many patients are aware of what they need to do to improve their health status and therefore decrease their morbidity. Nurses can assist patients to develop and maintain altered healthcare practices and this is recognised as an important advancement to their level of self-care.

One opportunity that is under-recognised in the management of CHD is the use of nurse-led clinics. A nurse-led clinic has been defined as having a focus on health rather than illness and an emphasis on life management rather than diagnosis and intervention. These attributes need to be clearly defined within the structure and function of the clinic. Nurse-led clinics are not new, but the benefits of these clinics and how they support positive outcomes for patients have not been well studied.

Reviews on Effectiveness of Nurse-Led Clinics

A systematic review on the topic of the effectiveness of nurse-led clinics for patients with CHD was completed in 2005 and identified five studies that had reviewed aspects of nurse-led clinics in relation to secondary preventative care of CHD (Page et al. 2005). These five studies evaluated interventions related to education, assessment and consultations. The interventions included the angina plan which was a nurse-led facilitated self help programme; nurse-led health education and motivational interviews for patients awaiting coronary artery bypass; audit and recall of patients initially assessed in a nurse-led clinic and recalled if the patients CHD symptoms or clinical assessment were poor; and two studies that provided secondary preventative care appointments by specialist cardiac nurses.

Clinical improvements were clearly demonstrated by the nurse-led clinics in all of the studies and these included a decrease in anxiety and depression; an improvement in quality of life, general health and lifestyle. Follow-up was improved in both nurse-led clinics and general practitioner groups of the studies and patients reported high levels of satisfaction. Other beneficial effects to patients were demonstrated, including a reduction in severity of angina and improved medication compliance. However, these were subjectively reported.

Subjective reporting has been questioned as to the reliability of self-reported outcomes (Kirvesoja 2000). However, subjectivity gives the patients perspective and ultimately this is what we want to influence and evaluate. It may be this perspective that will motivate the patient in improving their healthcare practices.

Motivating Patients for Self-Care

Many chronic disease sufferers will be motivated to attend a nurse-led clinic where they have the ability to improve life outcomes; whether it is a decrease in symptoms or an increase in the attribute they can undertake. Sometimes something as small as an improvement in how someone mobilises around their home or makes their own bed with no chest pain, is enough of an incentive for them to become involved in a service where they may be assisted to regain some function.

Additionally, general practitioners and nurses thought establishment of the clinics led to an enhanced service for patients. The nurse-led clinics are also viewed as an effective means to improve the scope and structure of care delivery, provide the ability to implement best evidence, and demonstrate a commitment to improving patient care. The benefits to patient care are what persuaded many clinicians to undertake the implementation of a nurse-led clinic. However, the sustainment of the clinics was affected by the lack of both training and resources available to both the nurse and the clinic.

Clinics Increase Job Satisfaction for Nurses

Nurse-led clinics provided benefits in addition to improved patient outcomes, including professional autonomy of nurse practitioners. In the systematic review both general practitioners and nurses thought that the clinics extended the nurse's role, increased their confidence, skills and job satisfaction. Nurses also sensed that the nurse-led clinics enhanced their relationship with the patient, due to the increased amount of time spent with the patient and the enhanced continuity of care.

continued on page 33

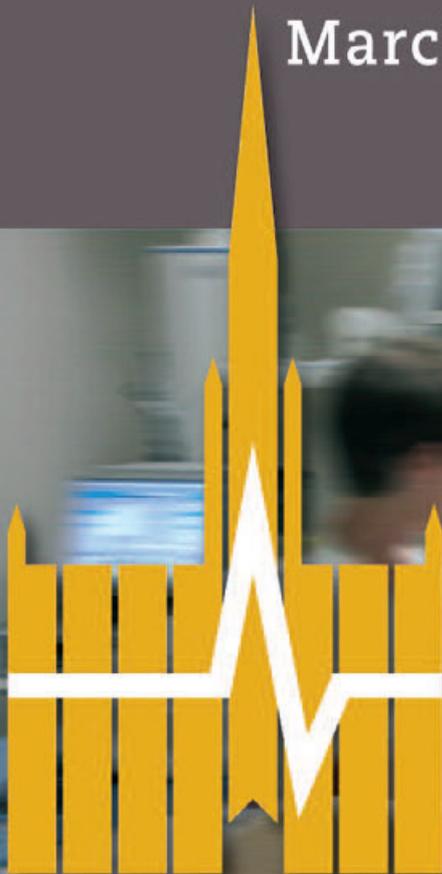
30th Anniversary

International Symposium on Intensive Care and Emergency Medicine

BACK TO BRUSSELS CONGRESS CENTER

(now: THE SQUARE)

March 9 - 12, 2010



Plenary Sessions, Mini-Symposia, Workshop,
Technical Forums, Round Tables, Tutorials, Posters

Endorsed by:

European Society of Intensive Care Medicine
Society of Critical Care Medicine
American Thoracic Society
European Society for Emergency Medicine
European Shock Society
The Institute of Critical Care Medicine
The Canadian Critical Care Society
Australian and New Zealand Intensive Care Society
International Pan Arab Critical Care Medicine Society
World Federation of Societies of Intensive and Critical Care Medicine

Meeting Chairman: JL Vincent

Email: jlvincen@ulb.ac.be

Manager: V De Vlaeminck

Email: veronique.de.vlaeminck@ulb.ac.be

Dept of Intensive Care,
Erasmee University Hospital
Route de Lennik, 808,
B-1070 Brussels, Belgium

Phone 32.2.555.32.15/36.31, Fax 32.2.555.45.55

Email: sympicu@ulb.ac.be

Website: <http://www.intensive.org>

**Posters: Deadline for abstract
submission: December 1, 2009**

A MULTIDISCIPLINARY APPROACH TO SYNCOPE

A Promising Answer to a Universal Dilemma



AUTHORS

Luis A. Serrano (above)¹
Wyatt W. Decker¹
Peter Smars¹
Win K. Shen²

Department of Emergency Medicine¹
Division of Cardiovascular Diseases,
Department of Internal Medicine²
Mayo Clinic
Rochester, Minnesota, US
serrano.luis@mayo.edu

The evaluation and management of syncope is often challenging to clinicians. A ‘well-appearing’ patient may present to the Emergency Department (ED) or outpatient clinic who may be at risk for malignant arrhythmias. Poor prognosis would inevitably result in extensive testing and hospital admission. The recognition of this dilemma has led to recent clinical investigations to assess specialised multidisciplinary syncope management units, involving experts in cardiology, emergency medicine, and a multidisciplinary team of health professionals to establish a potential cause of syncope while stratifying risks for long-term prognosis.

Developing a Standard Syncope Management Unit (SMU)

Several multidisciplinary efforts have been undertaken to develop efficient evaluation pathways to manage patients with syncope of unknown cause. They have combined elements from clinical guidelines, clinical decision rules and risk scores, such as the San Francisco Syncope Rule and the OESIL risk score with specialised critical pathways to enhance the diagnostic yield and practice efficiency of syncope

evaluations. Figure 1 (see page 31) illustrates both models.

In 2004, Shen and his colleagues published the Syncope Evaluation in the Emergency Department Study (SEEDS) (Shen et al. 2004), a single centre, randomised clinical trial, comparing the syncope observation vs. standard care for patients with intermediate risk of cardiovascular adverse outcomes.

The objective was to assess the diagnostic yield and hospital admission rates of patients with syncope of unknown cause. Patients who presented to the ED with syncope were classified according to their risk for subsequent cardiovascular adverse outcomes in high, intermediate and low risk strata. Intermediate-risk patients were randomised either to standard care (a brief evaluation in ED followed by hospital admission most of the time) or to a six-hour admission to a ‘syncope observation unit’ in the ED.

Echocardiography, tilt-table testing, electrophysiological consultation and outpatient follow-up were available to the ED physicians at their discretion. The study demonstrated an increase in diagnostic yield (diagnosis established in 67% of SMU and 10% standard care) and a decrease in the hospital admission rate (43% SMU and 98% standard of care), without affecting all-cause mortality.

In 2003, Brignole and colleagues published ‘The Management of Syncope, Referred Urgently to General Hospitals With and Without Syncope Units’, a prospective cohort study comparing six hospitals with syncope units and six without. The results revealed lower admission rates in the study group than the control (43% vs. 49%); fewer laboratory tests (75% vs. 86%) and brain computed tomographies and or MRI (17% vs. 24%) (see Table 1, page 31). The authors con-

cluded that management between groups was substantially different and to exploit its effect, the syncope unit (managed by cardiologists) should work in close liaison with the ED as well as other departments.

Multidisciplinary Approach to Syncope: Our Experience

Our institution evaluates around 600 patients with syncope annually in the ED and 2,500 patients in the outpatient clinics (medicine, cardiology, neurology, etc.), accounting for approximately 10 - 20% of the electrophysiology practice. This high volume of patients, combined with the multiple etiologies of syncope and a very diverse and complex population represents a diagnostic challenge to physicians from the ED to the inpatient/outpatient services.

In 2000, a multidisciplinary effort, led by experts in cardiology, electrophysiology and emergency medicine developed and launched the syncope observation unit in an effort to improve the triage, diagnosis, therapy and education of patients with syncope. The overall design involved ED assessment, observation unit evaluation or hospital admission and outpatient follow up at an arrhythmia clinic staffed by electrophysiologists, and neurology clinics staffed by epilepsy specialists and autonomic neurologists (see Fig.1, page 31).

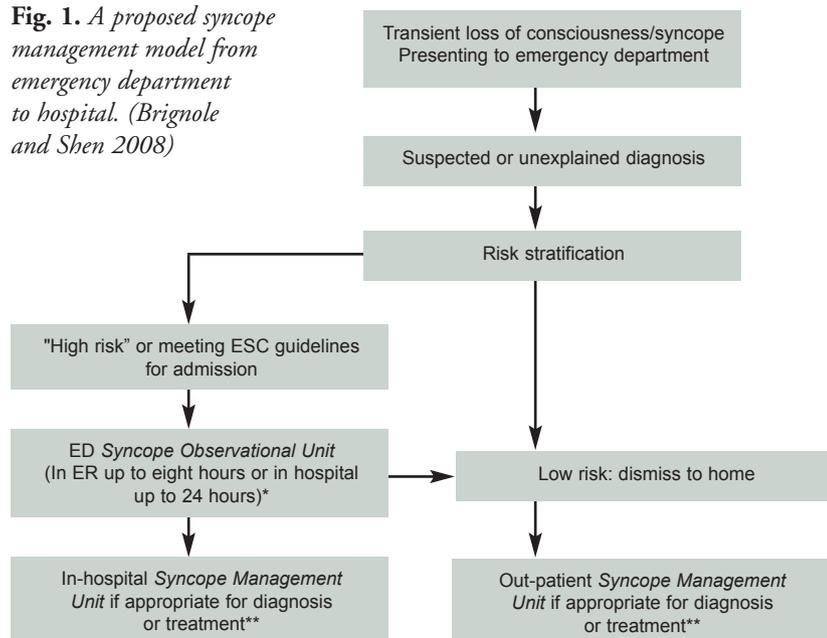
What is Needed for This to Work?

The success of multidisciplinary syncope evaluation depends on a combination of short/long term interventions in specialised units equipped with sufficient resources and expertise. Here are a few key principles:

1. Standardised assessment and guidelines

In the SEED study, patients randomised to the specialised unit received a standard protocol, which included continuous car-

Fig. 1. A proposed syncope management model from emergency department to hospital. (Brignole and Shen 2008)



Initial Evaluation:

- History, Physical Exam, Orthostatic BP, ECG (hematocrit & electrolytes if appropriate)

See risk stratification in Table 1 and ESC rules in table 2

ED Syncope Observational Unit:

- Trained personnel
- Cardiac monitoring
- Scheduled orthostatic BP checks
- Timely diagnostic testing (echo, tilt test, carotid sinus massage)
- Available subspecialty consultation

*The six-hour syncope unit evaluation was examined and validated in the SEEDS study. The 24-hour hospital unit evaluation proposed here is primarily based on two factors. Within 24 hours, the medical team should decide whether the patient will need to remain in the hospital for further evaluation/therapy or is ready for dismissal and outpatient management. When a hospital stay is under 24 hours, the patient can be managed under "observational" status without being admitted, thereby potentially reducing healthcare resource utilisation. **The Syncope Management Unit was developed in strict adherence to the recommendations of the guidelines of the European Society of Cardiology and validated in the EGSYS-2 studies.

diac telemetry for up to six hours, hourly vital signs and orthostatic blood pressure checks. Ancillary studies at the discretion of the ED physician, included echocardiogram, tilt table testing and carotid sinus massage. After the observation period, the patient was re-evaluated by the ED consultant and a decision regarding electrophysiology consultation was made. Information obtained from monitoring, testing, and consultation in the syncope unit contributed to the real-time component of risk stratification, which ultimately resulted in improved diagnostic yield in

the ED and reduced overall hospital admission and costs.

2. Communication between departments

Communication channels between ED supervising physicians and other specialties like cardiology, neurology and internal medicine need to be established "a priori"; availability on call pagers or phones to ensure a clear transfer of information between consultants, adequate follow-up and overall enhanced patient care. In our "conventional" practice, the triage of

patients without a diagnosis (often occurring due to time and resource constraints in the conventional ED practice model) is coordinated by the primary supervising emergency physician via telephone with the cardiology service. This usually results in admission for further evaluation.

The SEED study compared this conventional approach to the "syncope unit approach". After the observation period, with additional information from continuous monitoring, vital signs, echocardi-

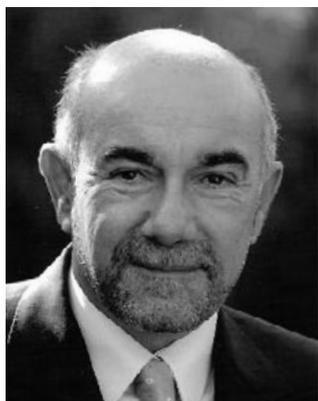
continued on page 42

Table 1. Syncope Management Unit Trials. (Chen, Benditt et al. 2008) (Adapted)

Brignole et al, 2003	Syncope unit in the hospital	Prospective cohort study within a prospective registry 6 hospitals with syncope units (study group) vs. six matched hospitals without syncope units (controls)	279 study group patients vs. 274 control patients	Fewer hospitalisations (43% vs. 49%) and tests performed (mean plus or minus SD, 3.3 plus or minus 2.2 vs. 3.6 plus or minus 2.2; P equals NS) among study vs. control patients Study patients underwent 38% more CSM and 87% more tilt testing NMS was diagnosed in 56% of study patients vs. 36% of control patients (P is greater than 001)
Shen et al, 2004	Syncope unit in ED	Prospective, randomised, single-centre study Syncope unit evaluation in ED (study group) vs. standard care in ED (controls) for intermediate-risk patients	51 study group patients vs 52 control patients	Diagnosis was established in more study patients than control patients (67% vs. 10%: P is less than 001) Study patients had fewer hospitalisations (43% vs. 98%: P is less than 001) and higher actuarial survival (97% vs. 90%: P is equal to 30) than control patients Syncope unit in ED increases diagnostic yield and decreases hospitalisations without affecting all-cause mortality

BP = blood pressure; CI = confidence interval; CSM = carotid sinus massage; DBP = diastolic blood pressure; ED emergency department; NMS = naturally mediated syncope; NS = not significant; OH = orthostatic hypotension; PCM = physical counter-pressure maneuver; RRR = relative risk reduction; SBP = systolic blood pressure

CARDIOLOGY LEADERS: PROF. PEDRO BRUGADA



INTERVIEWEE

Pedro Brugada
Professor of Cardiology
Head
Heart Rhythm Management Centre
University Hospital Brussels
Brussels, Belgium
pedro@brugada.org

There is no standard typical working day for me at the Heart Rhythm Management Centre.

Our day at the electrophysiology laboratory typically starts around 8:30 a.m. I am constantly moving from one intense and fascinating activity to another. I begin by meeting with Dr. Andrea Sarkozy, Director of the Clinical Electrophysiology Programme and Dr. Gian Batista Chierchia, Director of the Atrial Fibrillation Programme. We discuss the patients' characteristics and problems on location and start procedures with a clear diagnostic and potential therapeutic plan. After checking the arrhythmia programme and setting goals for the day, I move to my office with Kristien Van Caelenberg, my PR, administrative coordinator, and also my wife. We go through meetings with contractors, supporters, officers and companies before starting consultations.

Prof. Pedro Brugada tells Cardiology Management about the public and private achievements that have shaped his career in cardiology. We also learn about the scientific legacy left by himself and his brothers, as the first to describe 'Brugada syndrome', a hereditary disease characterised by sudden cardiac death caused by severe disturbances of the rhythm of the heart.

One of Kristien's major tasks is the fellowship programme. We have a permanent squad of six electrophysiology and pacing fellows from all over the world. Some relocate alone, others with large families. Managing the different needs of these fellows is not easy, and Kristien's role as "mama duck" means that she is frequently trailed around the department by a train of different fellows, who rely on her support.

We have great fun at the electrophysiology laboratory, playing with our cutting-edge equipment: three electrophysiology stimulators, high-tech recorders, three 3D mapping systems for electro-anatomical reconstruction and mapping of the heart and magnetic navigation. Our surgeon Prof. Francis Wellens and his team take care of the burning, freezing, and cutting involved in curing our patients. Dr. Carlo de Asmundi leads the technology section in cooperation with Head Nurse Marc De Zutter.

Investigating each individual patient requires more than just assessing their medical data.

My consultation is exactly the same. I personally see between 2,000 and 2,500 patients per year at the outpatient cardiology clinic and an additional variable number of children at the paediatric rhythmology centre together with Prof. Abraham Benatar. The large majority of patients come for a third, fourth or even tenth opinion. They carry massive data on

maps, USB drives, CDs and printed pages with all previous visits, results of investigations in other hospitals and data collected from the internet.

My first job is to put this aside, however, and ask the patient: "Tell me, what brings you to me?" and "What brought you initially to a doctor?" Many patients have straightforward problems that are quite simply solved. Frequently, however, I deal with patients diagnosed or suspected of suffering from Brugada syndrome or other inherited arrhythmias. As well as daily emails, patients come from all over the world to obtain answers to the hundreds of questions produced by an inheritable disorder. We have a close cooperation with the genetic department and our research nurse, Stefan Henkens, coordinates all necessary aspects for this very delicate population, including the social and the psychological ones with Marina, our psychologist.

Kristien and I are the last to leave the department every evening except Tuesday, when consultants have late evening consultations. Once out of the hospital, other planned "surprises" await us: The plane for a meeting in Japan or a local meeting with GPs for teaching purposes. From January to June and from September to December, meetings are scheduled typically every second weekend. There is not much time for a social life, but I do my best to make time for golf and to join friends and family.

Public honours throughout my career have meant a lot to me: but one private honour has transcended scientific achievement.

The public honours I have received during my career are very important. As a Catalan, my greatest honour was receiving the Josep Trueta Medal for Medicine from the Catalanian government, and receiving the gold medal from the Catalan Society of Cardiology. On a private level, the lecture that touched me the most was the one I gave at the cemetery of my village, Banyoles, when my father died in 1999. Before he died, we had the incredible opportunity to show him the first monograph on Brugada syndrome. We buried him with that monograph. The speech I delivered and the feelings of the very limited family audience at that time, I leave to your imagination.

The description of Brugada syndrome had an enormous impact on my career and that of my brothers.

The syndrome has had an enormous impact on my career and those of my brothers Josep and Ramon. We know that we have been lucky to create a scientific legacy. We also described Short QT syndrome and its genetic mechanisms and a familial form of pre-excitation. We can

now clearly state that Brugada syndrome went from a scientific curiosity with only eight patients to the reference point for the understanding of inherited disorders of the electrical activity of the heart. Without electricity, there is no muscular cardiac contraction, thus, no blood perfusion, and no life.

I had to fight to gain my first place in the cardiology department.

After finishing my medical studies at 22, and after one year as general practitioner in the Catalan Pyrenees and Tarragona, I went to the Chief of Medicine of the University of Barcelona Hospital Clinic, haematologist Prof. Cirilo Rozman to ask for a job as a trainee in haematology. He said I was too young and that I had to wait for one more year.

However, the imminent arrival of my first daughter Isabel, meant that such a wait was a luxury I could not afford. Paco (Francisco) Navarro-Lopez had just become the new Chief of Cardiology and teamed up with Amadeo Betriu and Gines Sanz to create the first real cardiology centre in Spain. Thus it was that I made my case for an available position as a resident in cardiology with Paco. Working with these three luminaries was a daily thrill. They were light-years ahead of the rest. The hospital clinic has main-

tained this modern-facing reputation ever since. My brothers Josep and Ramon still work there.

When I look back on my days as a medical resident, certain memories stand out.

I was a resident in cardiology at the department of cardiology from 1976 to 1979. There are many favourite memories that spring to mind during this unique period in the cardiology department. As a resident I was paid well enough, and as a man alone I could have afforded to rent a small apartment, buy one or two daily sandwiches and drive an old motorcycle. However, as a married man with a daughter, every single peseta was important. Paco, who knew that a single sandwich was too expensive for me, initiated a type of medical game so I could 'earn' my lunch. His real hobby was congenital heart diseases. On Thursday I would do cardiac catheterisations with him on children with congenital heart disease in the pre- echocardiography era. Our only clues were the clinical history, physical exam, ECG, and the thorax RX. He would then show me the ECG, RX and tell me the clinical history and physical findings. If I made the correct the diagnosis, he would pay for my lunch. I can tell you that no resident in cardiology ever learned so fast as I did!

continued from page 28

The review suggests that nurse-led care for secondary preventative care of CHD patients is an effective adjunct of supplementary care to general practitioner advice and care and is as beneficial as general practitioner care. The implementation of a successful nurse-led clinic is dependant on the nurse being adequately trained in the care of a patient with CHD and having clear and appropriate expectations formulated both within the clinic and within the relationship with the medical officer.

One of the studies included in the systematic review did a further follow-up study and describes four themes associated with

the successful implementation of a nurse-led clinic:

- Patient care (the perceived idea that the clinic will improve patient outcomes);
- Development of nursing skills (training and support issues);
- Team working (communication, support and sharing the same belief), and
- Infrastructure (staff shortages and financial incentives).

Conclusion

Nurse-led clinics have revealed both clinically sound and perceived benefits to the patient, by focussing on promoting health traits and putting emphasis on car-

diac management. Nurse-led clinics are an effective adjunct to general practitioner clinics; however the nurses should be adequately trained to be able to manage each patient's preventative care effectively and according to previously defined clinic guidelines.

The financial benefits have not been adequately studied, but perceived benefits from improved cardiac health and possible decreased admission rates will equate to the increasing number of patients with CHD becoming less of a financial burden on the healthcare system. Current community requirements would support nurse-led clinics as a preferred model of care.

LEADERSHIP AND COACHING IN THE HEALTHCARE ARENA

Understanding the Emotional Tools Required to Lead Your Team



AUTHOR

Dr. Franz F. Immer
Assisant Professor
Cardiovascular Surgery
Inselspital Bern
Bern, Switzerland

Also,
CEO
Swisstransplant
Swiss National Foundation of Organ
Donation and Transplantation
Bern, Switzerland
franzimmer@yahoo.de

ACKNOWLEDGEMENT

Iris Küenzi
Consultant & Trainer
Agility Communications
Thun, Switzerland

Hanneke Gerritsen
Mercury Urval AG
Bern, Switzerland

Medical professionals are accustomed to using an analytical approach and bearing responsibility as an innate part of their expertise. Good leadership, however, is not only about being competent in their primary clinical role. It involves a much higher scale of complex skills, both in management and communication. Medical leaders have to be effective and efficient at using each team member's expertise to advance the organisation. In this article I will touch on the core elements needed for effective leadership and coaching.

Analytical Approach

In a healthcare environment, specialists learn by deeply analysing the case and subsequently choosing the most important or most urgent one to solve. In their exam they have to take a closer look at the details underlying the problem. They take a rational and analytical approach and

and without consulting others. In some medical specialties interaction within the team is not possible due to a very hierarchical organisation.

Due to keen competition, this phenomenon cannot only be observed within a specialised team, but also within different teams in different kinds of institutions. In this context, professional and personal development of the team members is limited and adversely affects the advancement of the organisation.

Emotional Intelligence

To be successful as a leader, a more insightful understanding of individuals' needs and competencies is needed. One key element of leadership coaching for healthcare leaders is the development of emotional intelligence - their ability to process information of an emotional nature and to relate emotional processing to a wider cognition.

“Good leadership is not just about your primary clinical role - it incorporates an equal level of management and communication skills”

In normal praxis, people are promoted to a position of management or leadership due to their effort, results or good performance. They become leaders by default. But when they get there they soon realise that leadership takes something more than reaching goals or showing good intentions. Leadership is about getting others motivated, about the ability to affect human behaviour, while focusing on achieving the mission.

care less about their emotional environment. Focusing on themselves and the problems rather than others involved can lead to confusion, conflicts and a big ego.

Bearing Responsibility

Medical specialists are used to taking a great amount of responsibility and making decisions quickly. Many of these decisions are made without lengthy planning

Literature describes four types of abilities:

- Perceiving emotions – the ability to detect and decipher emotions in faces, pictures, voices and motions and to identify one's own emotions;
- Using emotions – the ability to harness emotions to facilitate various cognitive activities, such as thinking and problem-solving. Capitalising fully upon changing moods in order to best fit the task at hand;

- Understanding emotions – the ability to comprehend emotional language and to appreciate complicated relationships between emotions. Being sensitive to slight variations between emotions, and the ability to recognise and describe how emotions evolve over time and,
- Managing emotions – the ability to regulate emotions in ourselves and others.

Therefore, the emotionally intelligent person can harness emotions, even negative ones, and manage them to achieve intended goals within a team.

Understanding your own and other people's behaviour well enough will allow you to move yourself and others in the direction of accomplishing goals. It is important for healthcare leaders to develop a sense of awareness where one learns to control emotions, develop a sense of empathy towards others and be outstanding for interpreting and understanding the behaviour of others.

Through insights, leaders and their staff become more motivated to accomplish the mission. Personnel are the greatest assets in healthcare.

How to Improve Emotional Intelligence

How can we improve our emotional intelligence and what are the important aspects to be considered as a team leader? Here a few insights how leadership can be improved within a team with the aim to achieve a defined mission.

How to Harness Emotions

The ability to harness emotions, even negative ones, and manage them to achieve set targets within a team is mainly driven by the unconscious mind. The unconscious mind stores memories, makes associations and learns quickly, organises all your memories and represses memories with unresolved negative emotions for resolutions. It controls and maintains all perceptions.

External events are deleted, distorted and generalised by filters to finally provide an internal representation. Based on our physiology and on our state, a certain behaviour will be generated. This is common to all human beings.

Being aware of this, leadership requires respect for the other person's model of the world. Resistance in a team member is a sign of lack of rapport and reflects inflexible communication. People are not their behav-

of the different steps – team members can then think ahead and not only deal with the actual situation. Awareness of the right strategy is the glue between the individual and the team to achieve the mission. This is also an important aspect to get leverage for small businesses – ask the team members what will it mean to them to contribute to that mission?

If they do not identify any purpose to the mission, they cannot be said to support

“True leadership is not what happens when you are there, it is what happens when you are not there”

ours, which means that there are no unresourceful people, only unresourceful states.

Communicate Within Your Team

For leadership, calibrating one's behaviour is very important, as behaviour is the most important information about a person. It is important to notice and to communicate within your team that everyone is in charge of his own mind and therefore the results he achieves. It is also vital to be aware that they have all the resources they need to succeed and all the potential to achieve their desired outcome. There is no failure, only feedback.

Lead by Example

As a team leader you have to lead by example. Speak of team members and not of employees. You must set the standard for everyone in the team. Team members who do not work accordingly will lower the standard – these are so called paycheck people, doing only the minimum without taking responsibility.

In the process of implementing any new strategy, your team must understand each

it. In my opinion, paycheck people or people who do not fit into the team may have to be excluded from that team. It is not the people you fail to hire, it is the people you fail to fire that jeopardise your mission.

Be a Leader by Asking Questions

You can be a leader by asking your team questions. You must make sure that your team is supported – as a team leader you have to take care of this aspect. What you value most in your team members, you must show in your own behaviour.

The mission must be emotionally compelling and motivating - when the reason to make an extra effort in the team is strong enough, team members will do anything to achieve it.

If a problem is urgent enough, and the motivation is correct, a good leader will find a way to solve even the most difficult problem. At the end of the day it is important that your team knows you are the leader. True leadership is not what happens when you are there, it is what happens when you are not there.

OVERVIEW OF HEALTHCARE IN ITALY

A System in Transition

The Italian National Health Service (INHS) was established in 1978 to grant universal access to a uniform level of care throughout Italy, financed by general taxation. The INHS provides universal coverage and free healthcare at point of delivery to all Italian and European Union citizens. In spite of this, there are considerable variations in coverage and service quality between the richer regions of the north and the poorer ones in the south.

Type of Data	Figure	Date
Population (million)	58.78	2006
Live births/1,000 pop	9.2	2003
Deaths/1,000 pop.	9.8	2000
Life expectancy (years)	78 (male) and 84 (female)	2006
GDP (billion EUR)	1,572.2	2008
Total healthcare expenditure (% GDP)	9.0%	2006
Total healthcare expenditure per capita (PPP USD)	2,623	2006
% of healthcare system financed by public funds	76.4%	2004
Number of acute care hospital beds (per 1,000 inhabitants)	3.4	2005
Length of stay (average in days)	6.7	2006
Number of physicians (per 1,000 inhabitants)	6.2	2005
Number of nurses (per 1,000 inhabitants)	5.4	2004

Source: OECD, Eurobarometer, WHO, Istituto Superiore di Sanita (Rome), Nielsen and International Telecommunications Union (for Internet statistics).

Key Actors

The key operational actors consist of 21 Regional Health Authorities (RHAs) and approximately 200 Local Health Authorities (LHAs) which serve geographical zones with mean populations of about 300,000. Together, they are responsible for ensuring the delivery of healthcare services by means of public and private accredited hospitals and other facilities.

Reforms Shake up Roles and Responsibilities

In Italy, a major reform of the Constitution (Constitutional Law number 3 of October 18, 2001) radically modified the roles and responsibilities of the State and the Regions. At the national level, authorities are responsible for ensuring that the general objectives and principles of the health care system are met, including definition of the basic benefits package ('livelli essenziali di assistenza' or LEA, which must be uniformly provided throughout the country). The traditional welfare state maxims of universal coverage, dignity and equity have in recent decades been joined by principles of effectiveness and cost-effectiveness.

The Regions now have law-making powers on health protection, within the framework of fundamental principles defined by the State. All Regional Authorities have a considerable degree of powers to legislate on a regional basis and freely allocate funds received from the central government, in particular for healthcare delivery. Major policy decisions are however agreed by an inter-institutional 'State-Regions Conference', which is constituted by representatives of national Ministries and the Regional Authorities.

Full Spectrum Coverage

Healthcare services cover the whole spectrum of medical care, from visits to family doctors and specialists to in-patient treatment (tests, medication and surgery) and post-operative rehabilitation as well as ambulatory care

and outpatient treatment. The INHS also pays for part or all, of the cost of drugs and medicines. Emergency health provision is available to all residents (as well as visitors).

Tariffs, Reimbursement and Insurance

Hospitals are reimbursed by the INHS according to a national diagnosis-related group (DRG)-like system. National-level tariffs cover the cost of public hospital admissions throughout the country. The RHAs can add further tariffs for specific activities (such as psychiatric services), which are not covered by national tariffs.

Private hospitals are reimbursed to the same DRG-specified level, and additional costs borne by patients – through private insurance schemes. Many Italians and foreigners opt to take out private health insurance in addition to the basic State cover.

Among other benefits, private insurance provides freedom in choice of family doctors and/or specialists and the right to be treated in private hospitals. In many cases, private facilities reduce the waiting time for a specialist appointment or a surgical intervention. They also offer more freedom in visitation rights and standards of accommodation. However, the quality of medical care in State and private hospitals are roughly similar (surgeons typically work for both the State and private sectors).

Mixed Private-Public Models – a Beginning?

Certain Regional Health Authorities have reached agreements with private hospitals allowing patients to be treated under the INHS. This has shortened waiting lists at public hospitals, but lengthened them at private facilities. In addition, a court decision sometime ago ruled that patients whose life was endangered because of waiting lists could seek treatment at a private hospital without having to obtain

advance permission from the Regional Health Authority, and still be covered for costs by the INHS.

Financing

Financing of healthcare in Italy is mixed. The country has one of Europe's highest rates of private, out-of-pocket healthcare spending (about 25% of total). According to some estimates, almost 35% of Italians access private care in one form or another.

Although one of the principal goals behind the establishment of the INHS in 1978 was to quickly move toward a

restricted role, accounting for a 4.8% peak of total INHS revenues in 1996, and then declining to below 3% in 2002 after co-payments for prescription drugs were abolished.

Patients however continue to need to make out-of-pocket payments for non-prescription medicines and directly purchase private health care. An estimated 15% of the population has complementary private health insurance. This is either individually subscribed or offered by employers. About two out of three health insurance companies are for-profit while one third are non-profit organisations.

“Italy has one of Europe's highest rates of private healthcare spending”

national tax-based system, social health insurance contributions still represented more than 50% of total public financing for another two and a half decades. In 1998, social contributions were replaced by a regional business tax; this is supplemented with a national grant financed by revenues from value-added tax (VAT) collections to ensure sufficient resources for each region.

The traditional welfare state maxims of universal coverage, dignity and equity have in recent decades been joined by principles of effectiveness and cost-effectiveness.

Co-Payments

Out-of-pocket/private payments include co-payments for diagnostic procedures, medicines and ambulatory specialist consultations. Users have to pay costs of outpatient care up to a 36 euro ceiling since 2000. Co-payments for drugs and ambulatory services have a

Private Insurance

In contrast to EU countries, such as Belgium, Germany and France, Italy's private insurance sector is very loosely integrated to the public sector. As a result, private insurers tend to mainly substitute for INHS services rather than complement them. The most frequently used private health services covered by for-profit health insurance are diagnostic and outpatient visits, but their share in reimbursed monies is small. By contrast, inpatient surgical care accounts for only a fifth of demand but over two-thirds of total reimbursement.

Overall, the Italian healthcare system is one of continuing transition. In spite of occasionally severe criticism, not least from within the country, the World Health Organisation ranked the country as having the world's second best healthcare system, after France. (The World Health Report 2000).

HEALTHCARE IT AND E-HEALTH IN ITALY

Projects and Priorities



AUTHOR

Tosh Sheshabalaya
Contributing Editorial
Healthcare IT

Italy's approach to healthcare IT, and more specifically e-Health, has three facets. These are based on:

- National-scale techno-infrastructure requirements (the New National Healthcare Information System);
- e-Health Board, to harmonise regional and national policies and implementation, and ascertain that these are in line with the European Union, and
- Semantic considerations.

The overall goal of the e-Health programme is to improve the efficiency and effectiveness of the Italian healthcare system as a whole, and ensure adequate levels of healthcare services. In addition, the e-Health programme also aims to accelerate technological innovations and take-up of patient-centred healthcare services.

Responsibility for the programme is entrusted to a body called the Cabina di Regia. It is comprised of representatives of both the national government and the regions, and coordinated by the Ministry of Health.

New National Healthcare Information System

The New National Healthcare Information System (NSIS) was proposed in early

2001 by the Permanent Committee, which coordinates political issues between the central and regional authorities. On the policy level, the NSIS is intended to govern (support, oversee and monitor) the Fundamental Levels of Healthcare Services (Livelli Essenziali di Assistenza or LEA) required by law and guaranteed by the Italian National Healthcare Service for various clinical and care conditions.

At the technical level, the NSIS seeks to define a minimum dataset for analytical data to be used for health governance needs by the Italian authorities. Towards this, it has two primary goals:

1. To build an integrated system of individual health records, where patient information and the healthcare delivery structure are the central entities, but provide information on all levels of operating healthcare facilities, services delivered, as well as human and financial resources used by the patient(s).
2. To contribute to good governance principles of the health authorities by ensuring that all required data on individual healthcare is available (to the authorities, physicians and healthcare facilities) and usefully grouped, with adequate levels of anonymisation of patient identifiers to preserve privacy.

Broadly speaking, the NSIS faces and meets the needs of both patients (in terms of increasing the efficiency of healthcare access and delivery) as well as the authorities (who obtain a valuable tool for comparatively assessing hospitals and monitoring the overall healthcare infrastructure). The latter is an especially strong need, given the growing trend to decentralise hospitals and provide new, flexible care settings – such as revolving-door

treatments for the growing number of elderly patients with chronic diseases.

e-Health Board (TSE)

The permanent e-Health Board (in Italian, Tavolo di lavoro permanente per la Sanità Elettronica or TSE) was established in 2004. It was a joint initiative by the Health Ministry as well as the Ministry of Reforms and Innovations in Public Administration.

The TSE provides the forum and setting for technical consultations to harmonise national and regional e-Health policies in Italy, and to coordinate the implementation of e-Health action plans.

One of TSE's first major deliverables was a position document called 'Politica condivisa per la Sanità Elettronica' (Shared policy for e-Health). This adapts the strategic policy and implementation objectives in the European Union's 2004 e-Health Action Plan to an Italian context.

In Spring 2006, TSE released another major document 'Strategia architetture per la Sanità Elettronica' (Architectural strategy for e-Health), which contains the first high-level guideline and technical building blocks for designing a national e-Health architecture. Technical issues of direct concern are standards to represent collaborative healthcare delivery processes, data formats for electronic documents exchanged in the healthcare system.

In consonance with trends across the EU, the architectural approach recommended by the TSE considers the following requirements to be over-arching:

- Clinical information of the patient is available anytime, anywhere.

- The system respects the federated architecture of the Italian Healthcare System and Italian laws on privacy.
- The system has a high level of security reliability and availability.
- The system is based on the use of open standards.
- The system has a modular structure which enables a progressive implementation nationwide, and safeguards existing investments by being capable of interacting with existing legacy systems.

The full version of the Strategia architetturale is available from the website: www.innovazione.gov.it.

TSE has also launched a series of key e-Health pilots:

- e-Booking (five regions);
- e-Signature for operators (200,000 smart cards in 16 regions);
- Oncology Excellence Centres Network,
- Proactive prevention, telemedicine and tele-education, and
- General practitioners e-Health services network (covering 13,500 GPs in nine southern regions).

Semantic Considerations

The Cabina di Regia mentioned previously coordinates development and implementation of a program to develop semantic interoperability between different regional

health information systems and the new National Healthcare Information System. One specific aspect of this program (known as the Patient File project) has two goals:

- Re-engineering certain processes with a direct impact on digitally enhancing workflow (for example, patient registries, death certificates etc.).
- Defining a framework for EHR development at regional and national levels (which has been closely coordinated with the Veneto EHR project (described below).

Bricks Programme

The so-called Bricks programme, representing common elements and building blocks of the healthcare system, was launched in 2004. It establishes the semantic toolkit necessary to ensure a common language for:

- The classification and codification of concepts such as healthcare services, facilities etc.;
- The sharing of methodologies to measure and compare quality and efficiency of the Regional Healthcare Services such as waiting times, and
- Achieving a uniform approach in the generation of data and information for the Fundamental Levels of Healthcare Services.

The Bricks toolkit also helps to ensure interoperability in the information systems devel-

oped by the Regions, and by the local healthcare administrations, will all interoperate. It has been organised into 15 thematic projects (bricks), with each Region responsible for managing one specific project.

The Veneto Project

Overall, the key e-Health projects under the auspices of the Bricks programme, has been run by the Veneto Region and the Lombardia Region.

Veneto has been responsible for IESS - Integrazione per l'erogazione di Servizi in Sanità (Integration for Health Services delivery). This project, beginning with demonstrations and scaling up of pilots, has gone to the heart of the entire e-Health chain. It facilitates a direct online approach by citizens to healthcare services and professionals (hospitals, GPs, pharmacies).

The Veneto region has also been mandated to set up a functional Electronic Health Record (in Italian, Fascicolo Sanitario Personale or FSP) alongside online authentication of 105,000 smartcards with digital signoffs at two local health units as well as the setting up of an interoperability network for all local health units of the region involved with electronic booking and the Electronic Health Record.

The Lombardia Project

The Lombardia Bricks project (due to end in 2009) involves a Healthcare Extranet to securely link all actors in the wider healthcare delivery chain, that is beyond patient and provider to also include social services organisations, aftercare paramedic professionals etc. The Extranet, known by its Italian acronym SISS, tracks and records all events in the patient treatment cycle. The project is based on smartcards to provide access to the SISS Network.

The first phase involved prototyping, and ran from the end of 1999 until 2002. Between 2003 and 2005, it was extended across the Lombardia region. The second phase, which started in March 2002, is to be completed by September 2009 by when it is due to cover the entire country.

Healthcare IT and Quality

Decisions on investing in healthcare technologies have become increasingly important across the world. In 2001, Italy established a Health Technology Assessment (HTA) unit at the Gemelli University Hospital to support hospital CEOs in financial, quality and strategic-organisational decisions involving a full range of areas - from medical devices and pharmaceuticals drugs to biomedical instrumentation and IT systems. The Gemelli HTA Unit catalysed the first triennial Technological Investment Plan for the period 2004 - 2006. Other units have since followed suit.

Part of the inspiration for the HTA actually date back to the Italian National Health Plan 1998 - 2000, which set up a procedure for accreditation of healthcare providers (both public and private), based on an assessment of their infrastructure and human resources. The National Health Plan also called for developing a Programme on Health Care Quality to steer the Italian NHS to strive for a Six Sigma-style continuous improvement of all dimensions of quality.

TELECARDIOLOGY IN ITALY

An Overview of Current Applications



AUTHOR

Dr. Paolo Zanaboni
Politecnico di Milano
Department of Management,
Economics and Industrial Engineering
Milan, Italy
paolo.zanaboni@polimi.it

Telemedicine represents a good solution for the management of patients with cardiac problems. Telecardiology, in particular, guarantees continuity of care and the creation of integrated networks between acute hospitals and primary care, with a more rational and quicker management of patients. Additionally, telemedicine is particularly implemented where geographical barriers impinge on equity of access to health services. Italy, even if characterised

by a high population density (approximately 200 inhabitants/km²), is rich in isolated and rural areas that suffer from a scarcity of healthcare resources.

Telecardiology in Italy

Telemedicine projects have existed across Italy since the 1990s. The most diffuse telemedicine services in Italy include telemonitoring of people with chronic conditions and teleconsultation for specific cardiac events. In particular, the main applications cover the following areas: telemonitoring of patients affected by chronic heart failure or hypertension, patients implanted with cardiac devices, teleconsultation for general practitioners and for emergency.

Chronic Heart Failure (CHF)

Usually after a cardiovascular related hospital discharge, patients can be followed through a telemedicine programme. This management model requires a portable device for ECG execution and subsequent

transfer, by an analogue or mobile telephone, to a call centre, which stores it and acts as a point of contact between patients with hospital nurses and cardiologists. Hospital staff are responsible for the clinical management of patients, providing consultations or nursing triage, whereas the call centre provides technological and organisational support and, if requested, offers clinical support 24 h/day, 365 days/year. All patient data are stored on a web-server and available in order to keep the GP informed and to support future investigations.

Hypertension

Self blood-pressure (BP) monitoring is acknowledged to play an essential role in the prevention and treatment of hypertension, with benefits both for clinical outcomes and for therapy optimisation (Parati et al. 2002). An inadequate BP control could be due to incorrect patient management. The usual model for the management of patients with hypertension through telemedicine systems

Fig. 1. Telemedicine Studies

STUDY	PURPOSE	POPULATION	MANAGEMENT	FINDINGS
Antonicelli et al. 2008	To study the effects of home telemonitoring on mortality, hospitalisation rate, compliance, quality of life and costs.	57 patients randomised to standard care or to telemonitoring care.	Patients followed for 12 months. Monitored subjects received weekly reports on their clinical status and their management was modified accordingly.	Improvements in the composite endpoint of mortality and rate of hospitalisations. Better compliance with therapy and quality of life.
Giordano et al. 2008	To determine whether home-based telemanagement (HBT) decreased hospital readmissions and costs in comparison with the usual care (UC).	460 patients. 230 patients in HBT and 230 in UC. Five hospital departments in different Italian regions.	Follow-up programme over a one-year period. A scheduled transmission every week or every 15 days.	The rate of heart failure-related readmission was 19% in HBT group and 32% in UC group. Mean cost for hospital readmission was significantly lower in HBT group (843 euros) than in UC group (1298 euros).

requires a home BP monitoring device that allows a daily BP measurement and transmission over a mobile or analogue telephone line. Data are then reviewed by physicians, who can communicate the clinical conditions both to patients and to GPs and modify therapy during the ambulatory visits (e.g. every three months) based on the daily measurements of the previous period.

Cardiac Devices

The rise in new cardiac implantations leads to a consequent increase in the number of follow-up visits in hospitals for patients implanted with pacemakers (PM) or implantable cardioverter defibrillators (ICD). Remote monitoring of cardiac devices is an alternative to intermittent visits. It allows early identifica-

tion of device-related problems and changes in rhythm and symptoms and reduces unnecessary visits. These patients are well known by their specialists who, through the receipt of device data remotely transmitted by patients at home, can quickly and appropriately decide whether the patient needs a visit for device reprogramming, an emergency admission, a change in therapy or noth-

Fig. 2. *Self Blood-Pressure Monitoring Studies*

STUDY	PURPOSE	POPULATION	MANAGEMENT	FINDINGS
De Luca et al. 2005	To test the effectiveness on BP and total cardiovascular risk (TCVR) control of a network of specialists and GPs.	CampaniaSalute (CS) Network composed by 23 clinics and 60 GPs. 4,024 patients.	Two-year follow-up per patient. 1,979 patients in the CS Network (telemedicine group) and 2,045 patients outside the network (control group).	Telemedicine group obtained a better control of BP and TCVR than control group.

Fig. 3. *Cardiac Devices Studies*

STUDY	PURPOSE	POPULATION	MANAGEMENT	FINDINGS
Lunati et al. 2008	To characterise the management of patients and the potential impact of remote follow-up.	270 patients. 1,959 device interrogations.	Analysis of device-stored data from patients implanted with biventricular defibrillators (CRT-ICD).	Six months after implant, reprogramming is significantly less frequent, making remote follow-up a practical alternative.
Masella et al. 2008	To assess the feasibility of a remote monitoring service for the follow-up of ICD.	Five hospitals. 67 patients. 267 ICD recordings. Period: January - May 2007.	Patients observed for three months. Three scheduled remote visits and unscheduled remote visits whenever requested. Data reviewed by hospital clinicians.	Success rate of transmissions: 99%. Time savings for physicians and patients. Reduced inappropriate hospital admissions. High acceptance by all the users.

Fig. 4. *Studies of GPs*

STUDY	PURPOSE	POPULATION	MANAGEMENT	FINDINGS
Scalvini et al. 2001	To evaluate the reduction of ED and cardiological visits through a telecardiology service for GPs.	150 GPs. 891 patients.	GPs transmitted, through an electrocardiographer, an ECG to a receiving station, where a cardiologist reported the teleconsultation.	Reduction of 47% of emergency department admissions and of 95% of further investigations respectively.
Molinari et al. 2004	To test the teleconsultation service for primary care through the ITMS telecardiology network.	7,000 peripheral GPs. 106,942 patients. Period: 1995 - 2003.	GPs could use transtelephonic ECG to obtain teleconsultations by the telecardiology centre.	58% of patients had no heart disease, 26% had drugs adjusted, 11% were sent to their cardiologist for further investigations and 5% were urgently hospitalised.
Scalvini et al. 2005	To describe patients with atrial fibrillation (AF) followed by GPs using a telecardiology service.	655 GPs. 7,516 patients. 23 cardiologists. 1 call centre. Period: 2001.	GPs were encouraged to use the service (ECG reporting and interactive teleconsultation) for patients with cardiac problems.	AF detected in 719 patients. Problem solution by TC in 66.3%, further investigations in 9.9%, ED admission in 23.7%.

Fig. 5. Studies in Cardiac Emergency Management

STUDY	PURPOSE	POPULATION	MANAGEMENT	FINDINGS
Marzegalli et al. 2005	To shorten the time between the ambulance intervention and the transport to the hospital.	6,821 patients, 89 with acute ST-elevation myocardial infarction (STEMI). Period: 2001 - 2005.	Patients with suspected heart attack were rescued and their ECG transmitted by advances life support (ALS) ambulances.	In patients with STEMI the service shortened the time of delivery of therapy, helped to recover complications and allowed the triage for primary angioplasty.

ing, with a consequent optimisation of healthcare resources.

General Practitioners

Teleconsultation to support GPs is one of the most diffused applications. It allows provision of specialised support directly at the GP's office with a lower use of hospital resources. Additionally, this service removes the obligation for patients to visit hospital, a benefit for patients who live in remote and isolated areas, or whose life conditions make the trip difficult. For example, the Telemaco project in the Lombardy region is currently testing a teleconsultation service for GPs localised in small mountain communities, which aims primarily at contrasting the depopulation of these isolated areas characterised by socioeconomic and infrastructural problems.

Traditionally, the management model involves GPs who, provided with a portable electrocardiographer, ask the specialist for a teleconsultation through a trans-telephone transmission of ECG recordings and a clinical request. The network often involves a call centre with cardiologists available 24 h/day offering ECG reporting and interactive teleconsultation with GPs.

Emergency

Cardiac emergency management through telemedicine is provided by healthcare networks which involve ambulances, headquarters of 118 rescue service and coronary care or cardiology hospital units. Transmission of the patient's ECG and clinical parameters allows an early and accurate diagnosis and the assessment of

risk profile with a consistent reduction in time to treatment and mortality rate.

Conclusions

Cardiology management models supported by telemedicine demonstrated benefits in terms of better follow-up, support for GPs' daily activity, prevention of clinical changes, stimulation of self-management of the illness, improvement of quality of life, reduction of rehospitalisation costs and quicker treatment in cardiac emergencies. In Italy telemedicine services are not routinely adopted and reimbursed by the national healthcare system. Telecardiology is still in the project stage and the scientific community is trying to provide the decision-maker with further evidence for its reimbursement.

continued from page 31

graphic examination (as needed), and tilt table testing and carotid sinus massage (as needed), the patient was reevaluated by the ED consultant, and a request for an electrophysiology consultation could be made if deemed to be necessary.

In the absence of a presumptive diagnosis at this point, these efforts would result in the confirmation of the patient's risk for a cardiogenic cause of syncope and overall prognosis. Among patients with expected low risk for cardiogenic causes, most patients were dismissed from the ED to be followed in the outpatient clinics. Admission to the hospital would be arranged if additional treatments were required.

Electrophysiology consultation was available 24/7 via telephone or onsite to assess high-risk patients. The ED physi-

cian would contact the EP cardiologist and the testing regimen and final disposition of the patient would be reached by consensus.

3. Optimal follow-up assessment

Emergency department physicians and staff had direct access to the heart rhythm centre to arrange follow-up evaluation when a cardiac cause of syncope was suspected. Follow-up in other medical and neurological clinics could be arranged as well through a routine scheduling system among patients with a low risk for a cardiogenic etiology.

Conclusion

The multidisciplinary model for syncope evaluation represents a promising solution to a universal dilemma. We believe that

after validating the efficacy and cost-effectiveness of syncope observation units at multi-centre trials, the next step would be to develop a syncope facility model suitable for implementation at community and international hospitals; utilising a combination of elements from different departments in the inpatient and outpatient setting. The ultimate goal is to provide an efficient and cost-effective evaluation and triage of these patients while decreasing overall costs and enhancing patient's care and satisfaction.

Acknowledgments: Dr. Luis A. Serrano is supported by the Mayo Clinic CTSA-University of Puerto Rico Scholar Transition Award.

References for this article are available upon request to the Managing Editor at editorial@cardiologymanagement.eu

ITALIAN HOSPITALS AND THE NEW MANAGERIALISM

A New Organisational Model

AUTHOR

Elena Cantu

Lecturer

Department of Institutional
Analysis and Public Management
Bocconi University
Milan, Italy

Since 1978, the Italian healthcare system has been organised according to the National Health Service model (Italian National Health Service, or INHS). Coverage is universal and, theoretically, uniform throughout the country. In 2003, public healthcare expenditure accounted for 75.1% of total healthcare expenditure. The Italian healthcare system is tax-funded and most care is provided free of charge at the point of service.

How is Care Provided?

Care is provided by government entities - Local Health Units (LHUs) and Inde-

pendent NHS hospitals as well as private hospitals and professionals that are eligible for reimbursement when “accredited” by the relevant Region. The INHS has three tiers: the central government at the top; 21 regional governments in between; and 180 LHUs and 95 IHs at the bottom.

INHS staff (including about 660,000 people, 1.1% of the Italian population) are under national contracts; wages and salaries are based on position and age. General practitioners (about 55,000) are not INHS employees, but provide primary care and refer patients to higher levels of care. From 1978 to 1992, the INHS was characterised by centralised funding based on past expenditures.

Reforms Include “New” Managerialism

In the 1990s, the INHS underwent a major reform introducing managerialism,

decentralisation to regions and quasi-markets. Under managerialism, many hospitals were taken out of LHU control and established as independent entities (IHs); general managers replaced highly politicised boards of trustees; LHUs and IHs were given greater decision-making autonomy, but were also required to meet higher performance standards.

Under decentralisation, regional governments achieved greater control over LHUs and IHs, appointed their general managers, provided them with guidelines, and were expected to cover the deficits. Under this new arrangement, each region became a parent company with LHUs and IHs as its subsidiaries. So much so, that some claim Italy no longer has one National Health Service but rather 21 regional ones. At present, a further decentralisation process is under discussion, giving more power to regions on health and requiring that funding be collected at regional level, with an interregional/-

Table 1. *Types of hospitals operating in Italy*

Type	Ownership	Number 2005	Average size (number of beds, 2003)
Hospitals directly managed by LHUs	Region	529	182
Independent NHS Hospitals	Region	95	673
Public scientific institutions for diagnosis, cure and research	Region/State	21	220
Private scientific institutions for diagnosis, cure and research	Private	37	540
University hospitals	Region/State	12	
Classified hospitals*	Private/Region	53	188
Accredited hospitals	Private	540	89**
Not accredited hospitals	Private	86	n/a

* including those classified by the Ministry for Health as “Presidio qualificato ASL”

** number of accredited beds

Management in Radiology



European Society of Radiology

MIR annual scientific meeting

Management in Radiology
September 30 – October 2, 2009
Riga/Latvia

- Imaging in the Baltic States
- How to manage low budget imaging
- Managing the public face of imaging
- Making tele-imaging relevant
- Making imaging IT relevant
- Managing imaging equipment

WWW.MIR-ONLINE.ORG

equalisation fund to guarantee national equity on per capita funding.

Quasi-market mechanisms were expected to induce better performance by requiring money to “follow patients”. As a general rule, each LHU will reimburse other LHUs, IHs and accredited private providers for care given to its residents. Reimbursements are DRG based for hospital discharges and fee-for-service for outpatient services. Under this general framework, each region is free to design

Manager (GM) appointed by the region. He is accountable for his performance and could be dismissed, if deemed inadequate. The replacement of highly politicised Boards of Trustees with a GM was one of the most significant INHS reforms in the 1990s, marking a sharp departure from the traditional bureaucratic paradigm.

This spoil system showed some strengths but also weaknesses. In particular, regions were replacing their GMs too frequently. Nationwide, the average GM tenure was

“Under decentralisation, regional governments achieved greater control”

its own funding arrangements. Italy’s regions have consequently been experimenting with different organisational and funding models to achieve an acceptable combination of equity, efficiency, freedom of choice and cost containment.

The Italian Hospital System

Hospitals have always played a central role in the INHS. Table 1 (see page 43) shows the different types of hospitals operating in Italy in terms of number, ownership and size.

In the last few years, health policy has pursued a shift from hospital to ambulatory care, resulting in a sharp decrease in the number of public hospitals (from 1,068 in 1995 to 732 in 2003) and public acute beds (from about 300,000 in 1995 to 200,000 in 2003). In contrast, accredited hospitals have remained stable (about 530 hospitals and 50,000 beds), probably because they focused on rehabilitation, long-stay and chronic disease care traditionally. The current density of NHS beds is 4.8 for 1000 inhabitants (4.2 beds for acute care and 0.6 for non-acute care).

Internal Organisation

The head of each public healthcare organisation (LHUs and IHs) is a General

3.2 years between 1996 and 2003. This seemed too short a period for effective management, especially in view of the complexity of healthcare organisations; the marked discontinuities brought about by GM turnover in the absence of strong managerial systems and market discipline; and the destabilising effects of turnover expectations.

Traditionally, the organisational structure of public hospitals was fragmented into numerous small, independent departments (e.g. general medicine, nephrology, gastroenterology). Numerous publications had recommended that these departments merge into larger “divisions” or “clinical directorates” to reach an effective compromise between specialisation and integration, and create a team of clinical managers interfacing the professionals with the GM. Managerialism reforms encouraged public providers to follow this recommendation.

According to a survey in 2003, clinical directorates had been introduced by 92% of public providers and extended to all in-patient medical and surgical units by 77%. Despite the introduction of clinical directorates, the most important level of responsibility centres still corresponded to the traditional, fragmented departments.

Financing

As mentioned, the reforms of the 1990s significantly changed the funding system for public and accredited providers, from the traditional model based on past expenditures to a model where LHUs were financed on an adjusted capitation basis and money followed patients when they chose to receive care not from their own LHU of residence but from IHs, accredited private providers or other LHUs.

The purpose is to place healthcare organisations under further pressure to improve efficiency and quality of care and reduce waiting lists. The undesirable effect may lead to an excessive increase in the volume of services provided to LHU residents by other LHUs, IHs and private providers, where “excessive” means “unnecessary”.

Consequently, all the regions try to limit this potential distortion by means of:

- Differentiated fee schedules (according to the private or public nature of healthcare organisations and to their organisational complexity and case-mix);
- Lump sum funding for activities where DRG based or fee for service funding is deemed unfeasible or inappropriate (e. g. funding emergency departments);
- Expenditure ceilings and targets defined by the region for each single provider or negotiation of bilateral contracts between LHUs and providers; and
- Introduction of utilisation reviews to deny payment for services that do not meet specified appropriateness criteria and development of appropriateness guidelines especially for out-patient services.

[A notable exception to the above model is the Lombardy region, which had formally opted for a radical purchaser-provider split: all hospitals were taken out of LHU control, grouped where necessary and established as IHs. As a consequence, LHUs do not provide in-patient care and out-patient specialist care. This model implies a more extensive use of activity-based funding.]

continued from p.23

The successful changes reported in the dietary and physical activity results were reflected in the results for risk factor management, i.e. for overweight and obesity, blood pressure, lipids and glucose (see table 2).

Body weight was measured in terms of body mass index, overall weight reduction and weight distribution (central obesity). The initial goal for weight loss in the overweight and obese was 5 - 10% of total body weight. The EUROACTION nurses helped significantly more patients to achieve this goal than in usual care.

Blood Pressure & Cholesterol Goals

The nurse-led programme was more successful than usual care in helping patients attain the blood pressure goal of less than 140/90 mm Hg. This was achieved in coronary patients despite no difference in the prescription of blood pressure lowering therapies between intervention and usual care. It is probably attributable to the delivery of a professional lifestyle intervention and better compliance with prescribed medication.

Achievement of the total cholesterol target of less than 5 mmol/L was high in both intervention and usual care hospital patients despite significantly more pre-

scribing of statins in the intervention centres: 86% compared to 80%. In those at high risk in general practice, a larger proportion of patients in the usual care centres started off at goal for lipids compared to intervention. However, the difference in change from baseline to one year in achieving target was 12.7% in favour of the intervention group.

The EUROACTION nurses were required to screen for diabetes and impaired glucose regulation and manage blood glucose and blood pressure to the lower target of 130/85mmHg. With regard to blood glucose control in patients with diabetes at one year, the distributions of blood glucose between the intervention and usual care groups in coronary patients were significantly different and in favour of intervention. Blood pressure management was significantly better in diabetic patients in general practice with 39% of patients in the intervention group achieving the goal of 130/85mmHg compared to only 19% in usual care: an 18.8% difference.

Challenges of Leading a Multidisciplinary Team

Professional standing of nurses
Demonstrating effectiveness of a leader-

ship role for nurses was not without difficulties. Nurses have differing professional standing across European countries. Nurse coordinated care may, therefore, not be applicable to all health cultures and may be dependent upon training provision for expanding roles and physician/nurse ratios in a particular country.

Successful multidisciplinary teamwork

Another challenge was to ensure good team cohesion. The success of the preventive cardiology programme in hospital, where a dedicated multidisciplinary team was put in place, depended to a large extent on the dynamics of the working relationships within the team. Coordinating a team of expert professionals to run a programme is a challenge that demands respect for knowledge and skills. However, it requires leadership qualities that can direct and keep the team together despite individual differences. The nurses coordinating each one of these EUROACTION programmes were expected to have these qualities.

Challenging traditional models and roles

Communication to health professionals of the success of EUROACTION has been seen as a threat to some. This presented a steep learning curve for all concerned, not least the EUROACTION central team, to understand sensitivities, and also to understand that for some health economies, a nurse coordinated model of care, rather than a doctor led model of care has not yet reached its time.

Conclusion

EUROACTION has shown that standards of preventive care in general hospitals and general practices across Europe can be improved. This nurse coordinated, multidisciplinary, family-based, ambulatory programme achieved healthier lifestyle changes and improvements in other risk factors for patients with coronary heart disease and those at high risk of cardiovascular disease and their partners than those in usual care. For more information about EUROACTION please visit www.escardio.org/euroaction

Table 2. Risk Factor Results

	Hospital			General Practice		
	I n=946 (%)	UC n=994 (%)	% change (95% CI)	I n=1019 (%)	UC n=1005 (%)	% change (95% CI)
Achieving ≥ 5% weight loss in overweight & obese	19	13	6.2 (-7.1 to 19.5)	16*	7	10.4 (4.7 to 16.1)
Waist circumference <94 cm (men); <80 cm (women)	31 †	22		23†	15	
Achieving blood pressure goal	65*	55	10.4 (0.6 to 20.2)	58*	41	16.9 (2.0 to 31.8)
Achieving total cholesterol goal	78	71	6.6% (-5.8 to 19.0)	36	32	2.4% (-9.9 to 14.8)
Fasting blood glucose (in diabetes) ≤ 5 mmol/l	21†	9		29	22	

*p < 0.05 for proportions achieving target

†p < 0.05 for difference in distributions

Industry NEWS

Siemens Demonstrate Intra-Cardiac Echocardiography Catheter

Siemens showed off their ACUSON AcuNav V, the world's first intra-cardiac echocardiography catheter for volume imaging, at the 2009 Scientific Sessions of the Heart Rhythm Society in Boston, MA, USA.

With real-time volumetric information from inside the heart, the new ACUSON AcuNav V volume catheter is said to

improve therapeutic ablation procedures and other electrophysiology (EP) applications; facilitating workflow and improving performance in the EP lab. It provides physicians with high-resolution volumetric ultrasound information about the anatomy and the tools used during EP procedures to improve patient care and increase safety within the EP lab.

Hypothermia Company Acquired by Philips

Philips has agreed to acquire the assets of InnerCool Therapies Inc., a therapeutic hypothermia company, and wholly-owned subsidiary of Cardium Therapeutics, Inc. It will be acquired in an asset purchase transaction for 11.25 million dollars, and the trans-

fer of around 1.5 million dollars in trade payables. The transaction will reinforce Philips' leadership position in the emergency care market by adding body temperature management solutions to its existing product offering in this field.

Boehringer-Ingelheim Posts Solid Growth Results

The pharmaceutical company Boehringer Ingelheim again posted gratifying growth in local currency (+8.3 percent) over the previous year in the first six months of 2009. Consolidated in euro, this reflected growth of + 15.7 percent thanks to the positive exchange rates, with net sales of 6,388 euros million compared with 5,522 million euros in the first six months of the previous year.

The operating income developed equally well over the previous year. Currency ef-

fects played their part here, too, adding to the positive development of the individual businesses.

In the first six months, net sales of Boehringer Ingelheim again outpaced the growth on the world pharma market. Boehringer Ingelheim is again expecting sales growth in local currency in the year as a whole to outpace the world pharma market; for the tenth time in succession. Growth in euro depends greatly on the exchange rate trends of the US dollar and the Japanese yen.

Sonosite Appoints New Director

Sonosite has announced the appointment of Rodney F. Hochman, M.D., to its Board of Directors. Dr. Hochman has more than 35 years of hospital management experience and has held numerous executive-level positions in hospitals across the country. He currently serves as CEO of Swedish Medical Centre

and has led the organisation since April 2007. Prior to joining Swedish, Dr. Hochman served as executive vice president at Sentara Norfolk General Hospital in Virginia, managing the operation of five hospitals, as well as the organisation's medical group, legal and corporate compliance divisions.

Medtronic Win Damages in Patents Case

Medtronic announced that a federal US district court jury in San Francisco awarded it 57 million dollars in past damages, finding that AGA Medical Corp.'s manufacture, sale and use of its Amplatzer® Occluder and vascular plug product lines infringed claims of two US

patents owned by Medtronic. The jury also ordered that AGA pay Medtronic a royalty of 11 percent on future US sales of the infringing products through 2018. Medtronic is also asserting these same patents against W.L. Gore & Associates, Inc. in another case.

SpaceLabs Expands Carolina Partnership

Carolina Pines Regional Medical Centre has increased their relationship with Spacelabs Healthcare and installed a fleet of all-new bedside monitors and central monitors in their ICU. The new monitors join existing Spacelabs monitors in the hospital's "rapid assessment" chest pain department, emergency department, paediatric care unit and telemetry unit at the hospital.

The centre selected Spacelabs' modular Ultraview™ SL2800-series bedside monitors, which offer complete monitoring and workstation performance in a

single package. In addition, the SL2800 delivers networked charting, lab, intranet and HIS applications creating complete electronic records and allowing the caregiver to review information from multiple sources without leaving the bedside. Internal modules will allow the hospital to monitor an array of vital signs, including a complete suite of ECG parameters, non-invasive blood pressure, temperature and oxygen saturation. Vital sign measurements can be configured at each monitor for a specific patient by choosing parameters from the modules.

Key Seminars and Conferences

OCTOBER 2009

01 - 03 11th International Symposium on Echocardiography
Athens, Greece

<http://www.onaseio.gr/>

04 - 07 11th International Workshop on Cardiac Arrhythmias
Venice, Italy

www.venicearrhythmias.org

NOVEMBER 2009

17 - 19 Echocardiography Course
Brussels, Belgium (Erasmus Hospital)

www.intensive.org

DECEMBER 2009

01 - 03 15th Postgraduate Refresher Course
Brussels, Belgium (Erasmus Hospital)

www.intensive.org

02 - 12 EUROEcho Congress 2009
Madrid, Spain

www.escardio.org

13 - 16 Update on Haemodynamic Monitoring
Rome, Italy

www.intensive.org

Cardiology Management

28/7, rue de la Loi
B-1040 Brussels, Belgium
T: +32/2/ 286 85 00
F: +32/2/ 286 85 08
www.cardiologymanagement.eu

Publisher

Christian Marolt
c.m@cardiologymanagement.eu

Editor-in-Chief

Prof. Panos Vardas
eic@cardiologymanagement.eu

Managing Editor

Dervla Gleeson
edi.torial@cardiologymanagement.eu

International Editor

Edward Susman
ed@cardiologymanagement.eu

Editors

Tosh Sheshabalaya
Lee Campbell
Sherry Scharff

Guest Authors

M. Biffi
G. Boriani
L. Bower
P. Brugada
H. Cole
T. Conroy
H. Gerritsen
F. Immer
C. Jennings
B. K. Kantharia
I. Küenzi
J. Lester
M. Lewin
C. Marcassa
C. Martignani
A. Marzali
H. Mistry
T. Page
P.L. Temporelli
P. Zanaboni

Global Communications

Katya Mitreva
office@cardiologymanagement.eu

Dr Don I. Idrees

d.i@cardiologymanagement.eu

Creative Director

Aleksander Bugge

Production and Printing

PPS, Print run: 12,000
ISSN = 1784-6331

In Issue 2 - Winter 2009

COVER STORY

- Prevention: The True Costs of Heart Disease

KEY ARTICLES

- Special Focus on Echocardiography
- Sudden Cardiac Death in the EU: Are we Doing Enough?
- How to Run a Modern Cath Lab

CONGRESS HIGHLIGHTS

- EUROEcho Congress 2009

COUNTRY PROFILE

- Cardiology in the United Kingdom



Verified Circulation

according to the standards of
International Business Press Audits

Cardiology Management is
independently audited by
Accountskantoor Closset



YOUR GATEWAY TO
HEALTHCARE MANAGEMENT

EMC Consulting Group
The innovators in healthcare communications
28 rue de la Loi, B-1040 Brussels
Tel: +32 2 286 8500
www.emcconsulting.eu





NETWORKING AWARDS 2009



WINNING PROJECT
GETS EXTENSIVE
PRESS COVERAGE
AND €5,000 CASH

**SUBMIT YOUR
PROJECT SUMMARY
NOW!**

More Information on www.hitm.eu