

# EuroIntervention

Official Journal of EuroPCR and the European Association  
of Percutaneous Cardiovascular Interventions (EAPCI)

The creation of EAPCI in 2006 from the reunion of EuroPCR and the ESC Working Group on Coronary Interventions has launched an exciting and rewarding journey, translating visionary and generous dreams into reality. Thanks to the continuous support of the EuroIntervention Editorial team and Europa Edition, we were given ample opportunity along the road to share our objectives, goals, concerns, and hopes with the interventional community.

Put together, these EAPCI columns illustrate nicely the EAPCI “culture”. We hope that you will enjoy reading (again) some of these editorial comments.

Jean Marco, Chairman of the Board of Directors of EuroPCR  
Patrick W. Serruys, Editor in Chief of Eurointervention  
William Wijns, President EAPCI 2006-2009

## European Association of Percutaneous Cardiovascular Interventions (EAPCI)

William Wijns\*, President, EAPCI

After years of careful planning and the extensive and inspired groundwork developed between the leadership of Working Group 10, EuroPCR and the European Society of Cardiology (ESC), the EAPCI – the European Association for Percutaneous Cardiovascular Interventions – has seen the light of day. The mission of this new association, the EAPCI, is “to reduce the burden of cardiovascular disease in Europe through percutaneous cardiovascular interventions”.

After its official launch, following approval by the ESC General Assembly at the World Congress of Cardiology 2006 in Barcelona, Spain, the EAPCI has been quickly evolving as the platform for clinical and scientific exchange between all health care professionals involved with percutaneous cardiovascular interventions. These endeavours have grown out of a synergy between many elements, among which is notably this journal itself, along with the EuroPCR course and all activities of the former Working Group 10.

In practical terms, the creation of our association involves certain specific activities. To begin with, the EAPCI will actively contribute to the programme of the yearly EuroPCR course, which will become our official annual meeting. This journal, EuroIntervention, is the official organ of our association, and will continue in its goal of presenting the best of research and education in the field, including case presentations in the lively electronic format that you are becoming used to. Furthermore, the EAPCI will dedicate a large part of its energy and time to training, accreditation and Fellowship programmes.

In order to achieve its goals, EAPCI will rely entirely on a close collaboration with the national Working Groups of invasive cardiology throughout Europe, as well as abroad, aiming at improving the quality – and recognition – of interventional practice and care throughout the continent and internationally.

Lastly, the EAPCI will underline our will and vigour in integrating and

contributing to all other activities of the ESC, as they pertain to revascularisation and other percutaneous interventions. Needless to say, the European Association for Percutaneous Cardiovascular Interventions, EAPCI, will continue to contribute to the annual ESC congress, the FOCUS sessions, the Euro Heart Survey programme, as well as the preparation and implementation of Guidelines. And this is just the beginning.

Underlining all our activities, the EAPCI will work on fostering a mature, active and measured collaboration with industry partners, one that is based on a clearly defined code of conduct acceptable to all. Post-graduate education, improving patient access to device-based therapies and promoting clinical research represent obvious areas of common and shared interest between us and the industry, and we recognise the symbiotic relationship that we share with them. The leadership of the EAPCI is comprised of an executive board, the various chairs and co-chairs of the different EAPCI committees as well as advisors from the European Society of Cardiology and Europa Organisation.

All members of the former ESC Working Group on Interventional Cardiology will have their membership automatically transferred, pending their approval, as required by French law. For others who are now interested in joining EAPCI, let me take this opportunity to invite you all to fill out the membership form, located on our website (go to [escardio.org](http://escardio.org) or [europcronline.com](http://europcronline.com)). Needless to say, EAPCI is open to all medical and allied professionals whose main activity is percutaneous cardiovascular intervention, irrespective of their specialty and country of citizenship. I trust that you will be keen on joining an Association which, with your collaboration, will become the core of our professional life in the years to come.

This is our first official column, it is the start of a long process that

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has, itself, been born out of the research, the work, the dedication of many of you in our young and fast growing speciality. We look forward to sharing the future together.

## Executive Board

President: **Dr. W. Wijns**, FESC, Belgium

President-Elect: **Prof. C. di Mario**, FESC, United Kingdom

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Secretary: To be elected

Treasurer: To be elected

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Journal (ex-officio): **Prof. P. Serruys**, FESC, The Netherlands

EuroPCR Board of Directors: **Prof. A. Vahanian**, FESC, France

EuroPCR Board of Directors: **Dr. J. Fajadet**, France

Presently the EAPCI Board is organising the elections of the new Board members, including the Secretary and the Treasurer.

## Chair & Co-Chair of EAPCI Committees

### Communication Committee

Chair: **A. Baumbach**, United Kingdom

Co-Chair: **B. Chevalier**, France

### Euro Heart Survey Committee

Chair: **F. Weidinger**, Austria

Co-Chair: **J. Marco**, France

### Scientific Initiatives Committee

Chair: **F. Eberli**, Switzerland

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### National Membership Committee

Chair: **J. Fajadet**, France

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### Education Committee

Chair: **J. Marco**, France

Co-Chair: **A. Cremonesi**, Italy

### Fellowship Committee

Chair: **A. Lafont**, France

Co-Chair: **J. Nordrehaug**, Norway

### Accreditation Committee

Chair: **C. Di Mario**, United Kingdom

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### Clinical Initiatives Committee

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## ESC and Europa Organisation Advisors

CEO: **A. Howard**, France

Operations Director for EAPCI: **K. Deront**, France

CEO Europa Organisation: **M. Doncieux**, France

## The latest news from the European Association for Percutaneous Cardiovascular Interventions (EAPCI)

**William Wijns\***, President EAPCI

*O.L. Vrouwziekenhuis Campus Aalst, Aalst, Belgium*

As a reader of EuroIntervention Journal, percutaneous cardiovascular intervention must be your primary interest. If so, please take a few moments to read the following update news from your association, the European Association for Percutaneous Cardiovascular Interventions, known as the EAPCI.

EAPCI was formally launched at the World Congress 2006 in Barcelona as a registered branch of the European Society of cardiology. We share the ESC mission, albeit focused on our field of activity:

***“To reduce the burden of cardiovascular disease in Europe through Percutaneous Cardiovascular Interventions”***

and the keywords that govern our action are:

**Synergy  
Focus  
and Credibility.**

Even though so recently born, EAPCI is already able to offer you important assets, represented by the heritage of its proud parents (EuroPCR and Working Group 10):

- EuroPCR Course, to take place this year for the first time in Barcelona, on the 22nd-25th May 2007,
- EuroPCRonline.com, featuring outstanding educational content, and the EAPCI website accessible on ESCardio.org,
- Euro Heart Survey and Registry,

- A comprehensive Education-Training-Accreditation programme,
- and not to forget, EuroIntervention Journal itself.

For EAPCI, strengths and opportunities are many. The coalition formed by the EuroPCR team – representing nearly two decades of commitment to education and teaching – along with the European Society of Cardiology – “the” representative cardiovascular medical scientific society in Europe and beyond – is a unique model. The blend of both cultures will materialise strong synergies as we consolidate our current assets and explore new activities.

At a moment where our field is experiencing another wave of expansion, leadership will be needed more than ever. To this end, EAPCI will rely entirely on a close collaboration with the national Working Groups, Societies or other bodies representing interventional communities throughout Europe, as the building blocks of our action. EAPCI can only be successful when governed by a “bottom up” relationship with its constituency.

At the beginning of the three-year term of this Board, many new initiatives are being considered, but at this present time please consider what we already have up and running right now. EAPCI leadership is structured in 8 Committees, each having a well defined mission that will be further delineated on our website and future newsletters: Communication, Euro Heart Survey, Scientific Initiatives, National Membership, Education, Fellowship, Accreditation and Clinical Initiatives. Through your national representatives, you will be asked to join and engage in these various committees, making EAPCI an essential component of your professional life in the years to come.

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*EAPCI Board 2006-2009.*

*Rows from left to right and from bottom to top,*

- Marc van Sambeek, Keren Deront (EAPCI Office at ESC), Carlo Di Mario (President-Elect),*
- Antoine Lafont, Sigmund Silber, Darius Dudek (Secretary),*
- Martyn Thomas, Andreas Baumbach, Jean Marco, Jan-Erik Nordrehaug,*
- Alberto Cremonesi, Franz Eberli, Horst Sievert (Treasurer), Franz Weidinger, William Wijns (President),*
- Bernard Chevalier, Ran Kornowski, Jean Fajadet, Alec Vahanian, Alan Howard (CEO ESC).*

*Missing on the picture are Sally Vincent (EuroPCR office), Marc Doncieux (CEO Europa) and Patrick Serruys.*

## EAPCI, EuroIntervention and EuroPCR... together

**William Wijns\***, President, EAPCI

*O.L. Vrouwziekenhuis Campus Aalst, Aalst, Belgium*

### **A new beginning**

For many of you attending the EuroPCR this year the big difference will be the country we are meeting in. For the first time in the history of this scientific gathering we will be leaving France and heading for Spain and Barcelona. But for us, the EuroPCR has another aspect, one which sets it apart from all previous years, because this year it is OUR meeting as well.

We have said this many times before, but it values repeating: the EAPCI, the direct outgrowth of all our collaborative efforts – whether on the WG10, or in our national meetings throughout Europe, or in the EuroPCR itself – has been created as the next step in the evolution of our profession. From now on, and since our official founding last year at the ESC meeting, through our collaboration with this journal and the EuroPCR, we are all intimately connected – a symbiotic relationship that will only help progress our speciality.

### **A common goal**

In a recent interview, Jean Fajadet, whose specific role as the current chair of our international affairs and national societies committee is to “facilitate and optimize the communication between EAPCI and all national interventional cardiology working groups”, underlined our efforts. A key element in our founding philosophy is our dedication to building close collaborative relationships between ourselves and all national groups through formal and direct contact. The goal is simple, we need to incite, inspire and encourage active involvement by these national working groups with the EuroPCR and the annual meeting of EAPCI in order to be the vital organisation that we set out to be.

We must remember that the EAPCI welcomes all professionals whose main activity is percutaneous cardiovascular interventions and who want to participate in our common goals of clinical research, scientific activities, and education in order to improve interventional procedures and the quality of patient care. As an example of this, Jean points to such activities as the successful (and oversubscribed!) Fel-

lows course run last November in London by Carlo di Mario and George Dangas which offered preparation for future European certification exams in interventional cardiology.

More information on all our various activities can be found on our website at: [www.escardio.org/bodies/associations/EAPCI](http://www.escardio.org/bodies/associations/EAPCI)

### **You make the difference**

It is clear for those of us already active in the EAPCI that the difference is you, the individual practitioner. We are committed to building our speciality together, and your participation, whether on a local level, in our European-wide registries or meetings are crucial for all of us. It is for these reasons that the program of the EAPCI is of such seminal importance at this year's EuroPCR, because it underlines the reality of this new dynamic.

We look forward to your joining us there.

### **Highlights of these meeting include:**

#### **Update on EuroHeart Survey and European registries**

Tuesday, the 22<sup>nd</sup> May  
16:30-18:30 in room 5

#### **ESC@EuroPCR - the first disclosure of the new ESC guidelines on treatment of non-STEMI**

Wednesday, the 23<sup>rd</sup> May  
18:00-19:30 in room 5

#### **EAPCI General Assembly**

Thursday, the 24<sup>th</sup> May  
18:00-19:30 in room 5

#### **Awards ceremony – EAPCI Fellowship awards**

to be presented by Antoine Lafont.  
Friday, the 25<sup>th</sup> May - 12:00-12:30 in room 1

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## EAPCI: update on subspecialty accreditation in Europe

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In our last two columns we spoke about the basis of our association, its history and general goals, in this article we update the situation concerning the EAPCI and its involvement in the nuts-and-bolts discussions that are laying the groundwork for subspecialty education and accreditation in Europe today.

Within Europe there are two primary boards working towards the accreditation, harmonisation and coordination of cardiology education and training. In education, it is the European Board for Accreditation in Cardiology (EBAC) which offers an “independent professional peer delivered accreditation of educational events and products” recognised by 19 national professional medical societies within Europe. In training, the EAPCI is an active member of the European Board for the Specialty of Cardiology (EBSC) Coordination Task Force on Sub-specialty Accreditation. This task force was created in 2004, and is chaired by Jose Lopez-Sendon and Peter Mills, the EAPCI is represented by Carlo Di Mario. The EBSC itself was created in 1992 by the *Union Européenne des Médecins Spécialistes – Cardiology Section* (UEMS - CS), in cooperation with the European Society of Cardiology (ESC) in order to set the “standards of care” for European cardiology. Its role is to make recommendations for setting and maintaining the standards of training in terms of quality, content, institutions and the trainers themselves. It evaluates member states and works towards the harmonisation of EC standards in cardiology. The EBSC created the current task force in order to, “define and promote sub-specialty accreditation standards, requirements and procedures... and contribute to the overall coherence of accreditation within the specialty of Cardiology”. This task force acts in several ways: as a coordinating body for training accreditation support within associations and Working Groups in the ESC; in implementing accreditation; and working with national societies to anticipate and influence regulation. The task force becomes a point-of-reference for the varied subspecialties as they work towards devising

a common curricular template, developing common assessment methods and increasing awareness of European subspecialty accreditation development.

As you are perhaps aware, in Europe today the majority of countries offer apprenticeship, but no real certification subspecialty accreditation, and very few have any formal accredited training and recognised certification programmes. Peter Mills (see figure 1) speaking at the last EuroPCR, explained that the principles of accreditation must be readily acceptable throughout the community as well as being fully integrated, with a growing need to “complement the ESC core curriculum”.

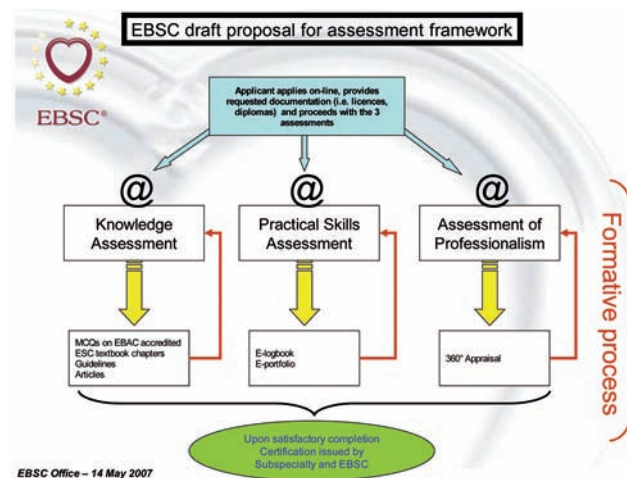


Figure 1. EBSC proposed outline for assessment framework.

A curriculum is now emerging through the experience of EAPCI members which aims to do this, assessing knowledge, skills and professionalism. Assessment methods are being debated, including the use of a European portfolio – or “e-logbook” – used to analyse the case mix that an aspiring interventionalist performs. Ideally

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a system will be put in place that assesses in a clear, comparable and repeatable fashion “intellectual development” with “direct observation of practical skills” that would demonstrate competence for the physician in such areas as patient selection, alternative clinical options or pre- and post- procedural care, etc.

The standardisation of accreditation in interventional medicine cannot simply apply to the curriculum itself, but touches on the role of the exam or knowledge assessment. There is a continuing discussion over “summative or formative” knowledge, taking into account that “learning should be part of assessment” and that the “most serious deficiencies in practice are not due to lack of knowledge”.

An effective training programme, training centre and trainer need to be defined. The emerging potential for simulators and virtual reality as training and assessment tools also needs to be quantified and qualified; their legitimacy depends on the development of a separate and recognised standard. To this end, an ongoing dialogue with industry has been developed, an essential cooperation allowing for “liaising with industry based programmes”

and special industry sessions, requiring a neutral and accepted evaluation method to insure the independence of each programme. Four companies have already agreed to work together toward helping define these standards.

Much has been accomplished, but much more needs to be put into place before a complete European system of subspecialty accreditation exists. CME credits, professional certification with European-wide and international recognition, harmonisation of standards and quality-of-care are the ongoing goals, and the EAPCI will take the lead in this process as the details and necessary components make themselves known.

As Peter Mills concluded in his remarks, there is a “strength” in “sound educational principles” and cardiology “must play a leadership role” in a Europe that “represents authority and quality, arising from expert consensus across countries and subspecialties, e.g., ESC guidelines”. And as you all can well understand from the above, there is much more to come from your Association about this programme in the near future as it continues to evolve and take shape.

## EAPCI: education and training programmes in interventional cardiology today

William Wijns\*, President EAPCI

Cardiovascular Center Aalst, Belgium

### Upcoming events

#### **2<sup>nd</sup> European Interventional Cardiology Fellows Course organised by the EAPCI at the Royal College of Physicians**

London, 15 - 17 November 2007

Course Directors:

Carlo Di Mario of the Imperial College London, United Kingdom and G. D. Dangas from Columbia University Medical Center, New York, USA

For registration and further information:

<http://www.europeancardiofellowscourse.org>

### Ongoing needs

As we round the corner of our first year of existence, the challenges facing our young association remain vast and complex, with the issues of accreditation and increasing grass roots support and participation paramount.

One of the cornerstones of our work is the listing and classification of all educational and training opportunities now available for interventionalists in Europe. This is not only essential for our members, but allows us to pinpoint weaknesses and identify those areas that still need to be developed. We can all agree that the availability of good training and excellent continuing education is essential in the continuing development of our speciality, and we acknowledge that much exists already. However if these opportunities are not apparent, easily consultable and accessible, then no training programme, no matter how excellent, will be of great use. Throughout Europe, whether you are a recognised expert, mid-career specialist, student or young practitioner, if you do not have a way of knowing what is available, you won't be able to

partake in the experience of your colleagues. In this case the good intentions, educational and training protocols and courses will be of limited value.

Our association, acting as a forum for these educational tools and experience, responds to a real need to fully illustrate what is being offered today. By doing so, it can also highlight what still needs to be done. This overview shows us our blind spots as well. For instance, we can see that there is a whole range of certain essential procedures for junior practitioners that need still to be covered, and here we can suggest that our partners, industry and others, develop useful tools for junior training (for instance in how to perform diagnostic coronary angiograms or right heart catheterisation or pericardial centesis, to name a few).

So while the EAPCI is not a training organisation per se, it can – and is – fast becoming, the umbrella organisation offering the greatest visibility for the myriad of educational and training programmes existing and being developed today. As an immediate vocation, this suits the EAPCI well, and we have begun our work in earnest, documenting the various centres and programmes, whilst beginning to provide, on our website, a centralised location for referencing all of this material, creating a veritable clearing-house of information for our speciality and craft<sup>1</sup>.

### Industry training programmes

At the EAPCI meeting last May during EuroPCR in Barcelona, leaders of our national constituents met and heard presentations by four of our industry partners on their portfolio of educational offerings. Their centres, funded by industry, yet independent of direct control, are each guided by well known senior European specialists, and provide many services, each different, with a wide array of subjects using virtual reality, focus groups, hands-on-training and much more at each of the different sites.

Here is a brief summary of what and who they are (further information can be obtained from our website, or directly through the different educational institutes).

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**The CrossRoads Institute of Abbott Vascular** grew out of the original training centre established by Guidant in 2000. It offers a wide range of courses under the academic leadership of Jean Marco and Luc Stockx. Marrying an “objective teaching philosophy to a high-tech approach”, it brings “hands-on, real-life methodologies” to its European and international public, either directly through the Brussels campus, or in its various programmes available worldwide. The Crossroads Institute offers “educational courses that address what healthcare professionals want and need to learn” to ultimately improve patient care. The Institute works through a variety of proven techniques leading to a high-quality and “unbiased training, peer-to-peer interaction, and state-of-the-art technology in a stimulating international environment.” The goal is for “professionals to return to their practice” with a take home message that leaves them “equipped with new techniques, practical skills, experience and clinical insights.”

**ACADEMIA** is supporting the continuing medical education and training at the Medtronic Therapy and Procedure Training centres. Academia’s mission is to create real impact, offering programs that are directly applicable in daily practice. The simulation programmes approach is to optimise patient outcome and improve performance in operations. Unique is the use the integrated real cases throughout the whole course, offering state-of-the art training designed by physicians for physicians with coaching techniques. Interactivity and procedural planning are the keywords of the programme. The independent Academia steering committee is led by Eric Eeckhout of CHUV Lausanne. Others members are Raoul Bonan, Bernard Chevalier and Philip Urban. The EBAC accredited courses can be experienced at the Medtronic centre in Tolochenaz, Switzerland, as well as Academia Live in Toulouse. Also Academia is travelling to many cities like Barcelona, Frankfurt, London, Southampton, etc.

**The Institute for Therapy Advancement** is an ongoing initiative of Boston Scientific and comes out of the historic pioneering work of the former Guidant Centre in Brussels. The independent course directors for the Institute are Carlo Di Mario in the UK and Faiez Zannad in France. Built on a concept which is not linked to any fixed location, with training facilities in Tokyo, St. Paul and now in Paris, the institute also sponsors proctor and fellows’ programmes. The training curriculum and spirit of the Institute is built around a desire to “provide neutral, objective courses to the cardiology community.” Focusing on daily practice, the Institute offers skills training along with the possibility of “sharing experience with peers, as well as key opinion leaders.” Work at the institute is composed of live transmissions, a fully operational cathlab and a virtual reality integrated learning system.

**The Cordis Cardiac and Vascular Institute (CC&VI)** was established to become a global network dedicated to “excellence in professional education in cardiac & vascular care.” Through the work of the 2007 core faculty, including myself and Martin Rothman on the advisory board, a series of integrated educational channels have been developed including interactive workshops and seminars (bifurcation, transradial and complexity workshops, meet-the-experts, and an extensive endo-neuro programme, etc.), as well as stand alone programmes at the CC&VI headquarters Hamburg, Germany. At a regional level the CC&VI, in partnership with scientific societies, centres of excellence, and the various faculty provide professional, continually updated educational programmes, with attention to research needs, as well as developing new courses as needed.

## EBAC certified programmes

In 2005, Heart published an editorial on the “rules of engagement” between industry and science. Entitled “Educational governance for the regulation of industry sponsored continuing medical education in interventional and device based therapies”<sup>2</sup> this piece echoed the universal sentiment that “the relationship between industry and clinicians in educational programmes needs to be regulated.” But what does this entail? The authors, Jean Marco, John M. Morgan, Luc Stockx and Faiez Zannad noted that “industry may be best placed to deliver educational programmes in ‘craft’ related specialties and particularly in areas where device implantation/technology based therapy has a major clinical role.”

For those of us both looking at education and involved in the development of ongoing programmes, the act of regulation, which might appear finite at first, is in fact a process, and like our discipline itself, depends on an open creative process allowing for a certain flexibility in order to fully respond and evolve with the science and practice itself. Ultimately the underlying key for the validity of any of these programmes remains the respected EBAC seal. The European Board for Accreditation in Cardiology (EBAC) accredits international Continuing Medical Education (CME) activities in cardiology in Europe. As a joint project of the European Society of Cardiology (ESC) and the Cardiology Section of the European Union of Medical Specialists (UEMS-CS), the role of EAPCI, an integral part of the ESC insures our part in this process and the legitimacy of our overall endeavour. By working in total

transparency with industry, we can approach, give counsel and help manage these training programmes, leading them through EBAC requirements to EBAC accreditation.

## The future

Alone, or nationally, none of us have the resources, financial or intellectual, to provide all that is needed in continuing education today, but together, on a European level and partnered with industry, universities, as well as governing bodies we can all move forward. Those of us who have participated in these educational and training programmes know that they can provide much more than just additional experience or re-validation of our skills. By creating new peer-to-peer relationships and offering us a different dynamic than that of our day-to-day practice, they are unique opportunities to forge the kind of professional community that gives life to our work. In carving the role of EAPCI as an essential part of the continuing educational dialogue for our specialty, our association can become the underlying structure on which that dialogues rests – this is the challenge and work of the EAPCI - our EAPCI – to excel as the ideal forum for our discipline as we continue to meet our goals as healthcare providers.

## References

1. EAPCI Communication Committee, Chair: Andreas Baumbach, Bristol, UK . Contact : [Andreas.Baumbach@ubht.nhs.uk](mailto:Andreas.Baumbach@ubht.nhs.uk)  
Visit: <http://www.escardio.org/bodies/associations/EAPCI>
2. Morgan JM, Marco J, Stockx L, Zannad F; *Heart* 2005;91:710-712.

## Measures in a speciality

**William Wijns\***, President EAPCI

*Cardiovascular Center, Aalst, Belgium*

As the EAPCI continues to evolve and define its role within the community, it finds itself naturally at the centre of a vast amount of information generated by – and for – the profession. Finding ourselves at the crossroads in this information highway brings with it the further responsibility seeing our role evolve, either in the direction of a simple clearing house for this information, or, in some way that needs yet to be fully determined, the guarantee, or at least measure of its quality and content. In the last EuroIntervention, we discussed and noted the various educational programmes being developed with the support of industry, and here today we see another aspect, an epidemiological one, that requires continued attention, vigilance, and definition.

In this issue of EuroIntervention you will find two articles, the first on “Percutaneous coronary interventions in Europe in 2005” and the other, entitled “An insight into the current use of drug eluting stents in acute and elective percutaneous coronary interventions in Europe. A report on the EuroPCI Survey.”

Both of these two articles represent two well know European registries, one being the long standing effort on behalf of the former European Society of Cardiology (ESC) Working Group led by Bernhard Meier based on numbers provided by national interventional working groups, the second, being the primary report of the EuroHeart Survey aimed at assessing PCI practice across Europe, including the use of drug eluting stents (DES) and passive stents in patients undergoing percutaneous coronary interventions (PCI). Over 9,000 patients have now been included in the European Heart Survey. There has been, and continues to be, considerable interest in these registries both on a country-to-country, as well European level via the ESC as well as internationally.

### The essence of Registries

The extraction of meaning from the various registries can be daunting, and while few doubt their critical importance, their utility requires some further reflection. As we examine and attempt to interpret them, it becomes clear that while it may be perfectly natural that there are different objectives on behalf of the different stakeholders – whether they be the companies, regulatory bodies, evaluation of practices, quality control, reimbursement, etc. – that this is a situation that needs to be truly ordered so that we might reap the greatest benefit. Similarly, methodology, definitions and quality can differ greatly from one registry to the next ranging from the “simple” collection of the number of procedures (as in Bernhard Meier’s ) to the most difficult today, which investigate long term follow-up with clinical outcomes.

As we face this onslaught of data the need for standardisation remains omnipresent. It was a little over three years ago, at the end of 2004, that we took a great step in that direction with the publication of “The Cardiology Audit and Registration Data Standards (CARDS)”<sup>1</sup>; but still, specific questions cannot be fully addressed until something as fundamental as case report forms (CRF) are prospectively designed to ask the right questions and collect the data that we truly need.

### What will the future be measured by?

In the foreseeable future our need for large long-term, patient-based data collections with predetermined questions, should remain the same as today, if not increase in importance – especially if these data sets are independent of direct industry involvement. In themselves, registries provide an incentive for participating sites and can act as a

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spur to quality and further the idea of benchmarking. It seems probable, both in terms of efficient interpretation and independence, that these national efforts should be coordinated and pooled at the European level, eventually even facilitated by the EAPCI itself.

There is a lack of wisdom in continually multiplying separate initiatives which can only further dilute our efforts and evade clear responses. Separate registries should seek a common denominator so that their results can be pooled, and clearly analysed, thus augmenting their pertinence.

Funding will probably remain a major issue because a good registry done in an exhaustive and correct way comes with a certain price tag which can be considerable. Source verification, development and assessment of the CRF, statistical analysis, adjudication of events, all these play into the overall budgets of these registries. At the same time, we cannot expect that industry will continue to pay for all this, nor should they. European Union (EU) funds, national governments and health care providers need to step into this field because so many of the issues elucidated in these registries go far

beyond simple device questions; one recent example, the Syntax trial, cost Boston Scientific over 40,000,000 euros and will touch on far more than this companies main products; to name only a few, what are our needs concerning the training of operators, what is the availability of operating versus catheterisation rooms, etc.

Like guidelines, registries are continuing to grow in number, and like guidelines, their usefulness in making sense out of our complex world remains valid. The EAPCI has a challenge to take up a leadership role, and become the natural forum for discussions leading to the design, implementation, and referencing helping to insure that these registries remain valuable tools.

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## EAPCI membership: converging worlds and techniques

**William Wijns\***, President, EAPCI

*Cardiovascular Center, Aalst, Belgium*

An association grows strong for many reasons: the quality of its offerings, the underlying validity of its existence, and above all, the members it has brought in.

Today there are over 10,000 of you receiving this journal... more than 10,000 potential members of the European Association of Percutaneous Cardiovascular Interventions (EAPCI), an integral part of the European Society of Cardiology (ESC) – an Association whose official publication you are now reading and which is open to all those who can honestly declare that “percutaneous cardiovascular intervention is your primary activity or interest”. And yet today, with so much recognised potential, our still young EAPCI only counts a little over 1,400 of you as members. Why? The benefits are many, and have been mentioned before and can be best consulted at our dedicated website ([www.escardio.org/bodies/associations/EAPCI/](http://www.escardio.org/bodies/associations/EAPCI/)) where you will find information not only on membership itself, but on our training and research fellowship programmes, as well as the upcoming meetings.

The EAPCI is open to all professionals whether you are PCI doctors, valvular specialists, cath lab nurses and technicians, non-cardiologists who are performing these procedures such as surgeons, radiologists or angiologists as well as researchers or doctors working in the device industry – all of you are eligible.

Membership benefits are manifold, and the areas of interest of the young EAPCI are constantly evolving through member participation. If we look at our current membership data, as of mid-February, we had 1,409 members – and while you can only vote if you are resident in one of the 50 official ESC member states – 93 countries throughout the world are represented. If we look at these numbers in a little detail, they are revealing of a number of trends, first a growing interest within Europe in our association, and second, the emergence of Asia as a centre of interest, not just for us, but – by their very active participation in the EAPCI – in what we are doing here in Europe.

### **An international presence**

Italy has the most participants with well over 100, followed closely by Poland and Spain which have over a hundred members as well. The U.K., Germany and France are close behind with between 50 and 100 members each, while other European countries such as Greece, The Netherlands and Belgium are fast approaching the 50 mark. Switzerland, Serbia, Romania and the Czech Republic are all represented with substantial participation, while there are now members from just about every European nation, including the Russian Federation.

Outside of Europe, our worldwide membership is of great interest to us, and strengthens our determination to grow. India and Iran have over 60 members each. The Mediterranean basin and the Near East – with Egypt (54 members), Turkey (45 members), Israel (41 members), Saudi Arabia (12), Libya (10), Jordan (10), Syria (8), Lebanon (8), Tunisia (7), United Arab Emirates (6), Yemen and Algeria (2) – are very active. Moving farther east Pakistan and Iraq all largely participate as well. Other regions of Africa are present with members from South Africa to Mauritius and Sudan; Central and South America are represented, with Brazil being the most represented of all these countries.

It is of course not surprising that North America is well represented with membership from Mexico to Canada, but what is very interesting to us, from our standpoint in the speciality, but also as Europeans, is that we have as many members in the United States as we now do in China. And if we add up all the other Pacific rim and East Asian nations that have joined the EAPCI to this date (and not including that very large participation from India we mentioned above), we have more members from this region than we do from South or North America (and for that matter, some areas of Europe): from Thailand (which has more members than either the US or China) down to Australia and New Zealand we have more than

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80 members in this part of the world today, and growing. And we are sure that, for instance, in countries such as Japan, there are many more potential members who are not aware that they can become part of the EAPCI.

## **Joining together**

What does all this mean? That we have room to grow, certainly, that we have even more reasons to urge you to join, absolutely, because together we have far more influence than each of us alone and together we can make a true difference in the evolution of our practice.

We strongly believe that advancement requires collaboration and teamwork and a strong commitment to being inclusive – open to all that might pertain to achieving our goals of improved care and practice. This is true both for interventionalists specifically and for medicine and healthcare in general. While this might all seem obvious, and just mere rhetoric, it can have a real impact by the work we do as a group. Becoming an active member of an association such as the EAPCI, which is firmly based in Europe, committed to advancing medical education and healthcare – and at the same time has a clear international vision – is just one concrete way of making these words reality. There is a certain force in

involvement and organisation. The more we are, the more influence we have over our educational offerings, our accreditation, and our viability as players in the increasingly bureaucratic game of healthcare. And we cannot emphasize enough how much you are all welcome in the EAPCI, all you who work in our field – from surgeons to radiologists, cath lab nurses and technicians, industry researchers and doctors... all of you and from every country have a role to play in our association.

A decade ago, as the computer age entered the mature stage that we know today, the term on everybody's lips was convergence. Convergence between images and idea, between what at the time were the separate domains of video and television and the computer itself. Today, with the vast developments in technique and understanding in medicine and fast advances in certain specialities we are starting to see another such convergence, a convergence between the different specialities themselves, as well as a convergence of skills and cultures. Today we know that this advancement requires, more than ever before, not only vision, but a group effort which can only be strengthened by the kind of participation that associations such as our own represents.

We encourage interaction and exchange, we grow by working together. Become part of our world, your world and join the EAPCI.

## Percutaneous Cardiovascular Intervention The time has come for a big change...

“Στου κουφού την πόρτα όσο θέλεις βρόντα”

«Il n'est pire sourd que celui qui ne veut rien entendre»

“There is none so deaf, as he who does not want to listen”

**William Wijns\*, MD, PhD**

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*Disclaimer: The content of this editorial only reflects the opinion of its single author. One should not assume that it is endorsed, even in part, by the European Society of Cardiology (ESC), EuroPCR, or the European Association for Percutaneous Cardiovascular Interventions (EAPCI).*

Nobody can speak on behalf of Andreas Grüntzig, certainly not me. Yet if he was to come back, for sure, he would be entitled to be immensely proud of his achievements. His legacy has translated into several new chapters in the history of medicine, pushing every other discipline, not just cardiovascular care, towards less invasive forms of treatment, by launching a new era of device-based therapies.

Our field has blossomed at an incredibly fast pace, through relentless imaginative research and daring innovation, all of which only became possible thanks to the billions of entrepreneurial investment that went into the cycle of inventing, developing, studying, validating and eventually marketing new devices.

Take for instance percutaneous coronary intervention (PCI). The technique has matured through successive quantum leaps of technological improvements, from plain old balloon angioplasty to the currently available sophisticated drug-device combinations. Indeed drug-eluting stents (DES) have reduced drastically restenosis rates, at last. Since – and because of the increased durability of its results – indications for PCI have expanded and many of the previous standards of care have been disrupted or made obsolete. Paradoxically, now that the technique has reached adulthood at the advanced age of 30 and has become more efficacious than ever before, its value is being strongly challenged, if not questioned. The late recognition of the rare safety issues that are associated with DES<sup>1</sup> has triggered a period of intense scrutiny, scepticism and sometimes animosity on behalf of non-invasive cardiologists, cardiac surgeons, journalists or lawyers. The publication of randomised trials

that do not favour indiscriminate use of PCI such as OAT<sup>2</sup> or COURAGE<sup>3</sup> fuelled the opposition even further. Allegedly, too many patients are submitted to device-based therapies, some of which are either insufficiently validated or poorly indicated. Above all, PCI specifically is not cost-effective and the value for money of DES is limited. Third parties are increasingly often inclined to divert resources from PCI into other life-saving therapies.

The reaction of the colleagues in the field has often been emotional, particularly in the United States. Attitudes have included paranoia, denial, mud wrestling or autism, all being obviously inappropriate. Others colleagues kept exposing the wealth of trial-based evidence that supports the use of PCI and other device-based therapies; yet, the magic is gone. The scientific validity of the evidence that we have accumulated is shaken. The robustness, the relevance, if not the honesty of the reported data are questioned altogether. In the eyes of many, we, interventional doctors, seem to have lost a great deal of our credibility.

Perhaps it is time to reflect upon ourselves. Did we indeed go wrong and if we did, when and why?

The present editorial is an analytical (at times psychoanalytical) exercise that attempts to understand why we got in trouble, what should perhaps be done differently and how we can possibly restore professional leadership. These thoughts have matured over several months and some of the arguments were presented in London on January 23, 2008 at the annual conference of the British Cardiovascular Interventional Society (BCIS).

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The present editorial is outspoken and not politically correct. The risk does exist that malevolent readers will use statements out of context, to serve their own interest. My only hope is to stimulate your thinking and perhaps, contribute at least in part to triggering the big change that is needed, urgently, or else we may soon lose our freedom to operate.

### **Too much focus on the technical**

Today, PCI and other device-based interventions are mostly perceived as stand-alone, technically-driven procedures. Unfortunately, they are seldom considered as an additional mode of therapy that is complementary to already existing ones.

Because of the very nature of the daily activity of the interventional cardiologist working in the catheterisation laboratory, much of her/his attention has been focused on instrumental, technical issues. Our field has remained very much a “work in progress” from the onset. As a result, evaluating the latest device iteration, keeping up with the most recently released tool-kit and learning how to adequately use the more complex technologies (typical examples are rotary ablation or vascular brachytherapy), has consumed a lot of energy. Less attention was given to equally relevant clinical matters. The situation is very different with surgical procedures. Surgeons undergo extensive and long-lasting periods of training during which technical matters are dealt with in great detail. Once fully trained, the surgeon reproduces the painfully acquired know-how during immovable “operating” procedures. Instead, we seem to be continuously running after the latest innovation and eager to test the newest approach, a perceived “must” since the field is constantly making progress. There are however major drawbacks. All that is new is not necessarily worth the change. Many novelties do not portend a significant incremental improvement, sometimes the opposite. Resources and energy are wasted on trivia and the more global perspective is easily lost given the excessively narrow focus on the technical.

### **Device-oriented instead of patient-oriented evidence**

Our key opinion leaders are often stressing the fact that progress in interventional cardiology is supported by numerous studies and trials, unsurpassed by any other medical discipline. Correct. However, the overwhelming majority of these trials are addressing technical matters, use surrogate endpoints, mostly derived from mandated repeat angiography, and did initially not require follow-up beyond one year after device implantation. This is candidly acknowledged by the consensus publication of the Academic Research Consortium which stated the following:

“The optimal basis for DES evaluation should be overall cardiovascular outcomes from the patient’s perspective...These outcomes reflect the complex interplay between device performance, revascularisation strategy, secondary prevention, and key patient descriptors.”

Instead, the vast majority if not all published stent trials have addressed device-oriented endpoints. Consequences are far-reaching: device-oriented randomised studies are financed, designed, powered, conducted, analysed and reported under tight

control by the industry. The questions asked pertain to superiority or equivalence of one device versus the other, leaving essential clinically-oriented questions unanswered. Hoping to provide the data that would justify the replacement of the old (cheap) by the new (expensive) device, trials failed to ask which patient or lesion subset would benefit most from treatment with the new and more effective device. Physicians did extrapolate the outstanding results obtained in selected populations to all-comers. At the end of the day, much was known about the results of DES in those who needed them the least (on label use). Limited randomised data or observational data of lesser quality derived from post-marketing surveillance registries only provided weak evidence to support the use of DES in patients and lesions subsets needing them the most (the so-called off label use). Very disturbing to regulatory authorities was the observation that the reduction in restenosis seemed to be smaller (by half!) in real life practice than in low-risk, selected trial populations<sup>5,6</sup>. This is because protocol mandated repeat angiography artificially inflates (doubles) re-intervention rates. Not surprisingly, independently performed health technology assessment studies turned out to be unfavourable. When the interrogations regarding the long term safety of DES exploded, both the profession and the industry were initially unable to provide definitive answers. The matter is indeed complex since death and myocardial infarction, the most frequent clinical presentations of stent thrombosis, are at the same time part of the natural history of coronary disease itself<sup>7</sup>. However it soon appeared that stent thrombosis rates had been initially underestimated due to the restrictive definitions applied in the trials. In addition, one has to admit that none of the randomised trials on DES are adequately powered to address without ambiguity clinical outcome and hard event rates. Diametrically opposite conclusions were drawn from two different meta-analyses of the same randomised dataset. In this Journal<sup>8</sup>, Daemen and Serruys were blaming regulatory bodies in Sweden for overreacting to the SCAAR I results. I am afraid that the regulatory yo-yo only mirrors the data yo-yo. Still today, one set of registry data is claimed to show mortality benefit, another set shows the opposite, while none of such data can reliably make this type of statement. Perception by the outside world is dreadful: we do not know what we are talking about, and in any case, as a group, we can barely be trusted...

### **Patterns of interventional behaviour**

It appears that the frustration accumulated during decades of failed attempts at fighting in-stent restenosis was released at once with the emergence of DES. Irrational behaviours were liberated leading to enthusiastic application of PCI in the absence of evidence to virtually all possible subsets, including unprotected left main stenosis in good surgical candidates or patients with multivessel disease and diabetes. Soon, the catharsis was somewhat tempered by concerns of escalating costs for multiple stenting and late stent thrombosis. Unfortunately, some of us seem not to realise to which extent skewed behaviours may potentially degrade the credibility of our profession: self-referral, conflict of interest issues, intervention driven by oculo-stenotic reaction, poor or incomplete patient information. Still today, demonstrations of arrogance, show-off or

silly humour remain all too frequent during live courses or lectures. What is the purpose of projecting these damaging slides presenting begging surgeons queuing in the unemployment line? In reality, we all know that adequate problem-solving requires a team approach. In this edition of EuroIntervention Journal, we discuss the power of consensus-based decision making, to the best interest of patients<sup>9</sup>. Together, we achieve more...

### **Repairing professional credibility and leadership**

Restoring professional leadership will be necessary to balance short-term demands with long-term needs, the continued drive for technological innovation with the legitimate right of patients for improved long term outcome. The current general attitude of interventional cardiologists towards innovation is characterised by enthusiastic, immediate endorsement. A healthy dose of scepticism needs to be re-introduced. Physicians should refrain from compromising with the agenda of the industry. In the long-term, confusion of interest is potentially damaging for everybody, including our industrial partners, as demonstrated by the current situation. In their thoughtful editorial, Harrington and Califf<sup>10</sup> are advocating a different partnership with industry as well as with regulatory bodies and payers, involving self-control and respect of each others' prerogatives and expertise. Clearly, the strength and duty of practising doctors, even invasive cardiologists, is to speak on behalf of their patients and to concentrate on patient-centred issues. Of course, the burden of the proof for technical matters belongs to the industry. However once the new product has been sufficiently validated to enter the clinical scene, independent modes of investigation as well as alternative funding should be secured, particularly when it comes to studying strategic issues regarding the respective role of different modes of therapy.

### **Percutaneous cardiovascular intervention: overrated as a technology, undervalued as a therapy**

The excessive focus on technicality and the never ending public controversies on the respective merits of discrete products, often held on the market place (literally), have contributed to devalue percutaneous cardiovascular intervention as a therapy and those who practice it, as a professional group. We ourselves have allowed the scope of our field to shrink down to material trivia, while failing to promote the life-saving indications of these procedures. When applied to patients with acute presentations of the disease, PCI is indeed reducing mortality, non-fatal infarction and stroke, with treatment effects superior to any other strategy. Providing this service to the community, improving procedural outcome through

innovation and promoting implementation and proper funding with regulatory bodies and payers shall be the principal focus of our action. Taking the lessons from a recent past will hopefully prevent similar mistakes to be repeated, as we engage in the percutaneous treatment of structural and valvular heart disease.

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## Together we achieve more...

**William Wijns\***, MD, PhD, FESC, President EAPCI  
**Jean Marco**, MD, PhD, FESC, Chair of the Board of Directors of EuroPCR  
**Marc Doncieux**, CEO Europa Organisation

While taking part in the 2008 vintage of EuroPCR, the annual meeting of the EAPCI (the European Association for Percutaneous Cardiovascular Interventions), you may wonder why we selected as the dominant theme, the seemingly obvious, yet somewhat dull statement: **“Together we achieve more ...”**

As a matter of fact, at the present stage of evolution in the field fulfilling such an objective is both critical and not at all trivially within reach.

After decades of explosive technological innovation, we have reached a stage where a given condition can be treated in five different ways, leaving the choice between perhaps ten different options for each strategy. Which of the 20+ CE marked drug-eluting stents shall I recommend for this particular lesion subset? Should this chronically occluded right coronary artery be left as is, or recanalised from the left through the septum after four hours of a glorious battle, or receive a bypass using the ancient surgical approach? And what about the elderly person with critical aortic stenosis, or the renal transplant patient who has carotid disease, or...

Today, patients and physicians are torn between the (too) many options available to them.

As is always the case during periods of rapid progress, there is a palpable tension between conservatism and modernism. Well validated therapies are perceived as old-fashioned by technology aficionados. The results of newer approaches, that are indeed often remarkably innovative, remain uncertain for the long-term for obvious reasons. Opponents and sceptics will argue that their wide application should be constrained until proven equally safe and at least as effective as the previously established standard of care.

Nurturing the tension even further are the unavoidable turf battles between specialists of different disciplines, or sub-specialists within a discipline. These battles are inherent to the process, especially

when truly innovative modes of therapy emerge. True innovations are disruptive of existing practices. When it is perceived that significant practice changes could result from the adoption of a newer form of therapy, defensive behaviours arise. This is perhaps understandable, usually not very efficacious, and hardly justifiable since they are the expression of a small, self-interested minority. By contrast, such attitudes indicate exactly how to resolve the tension and where the solution might come from.

**Consensus** is the solution, because what is universal among mankind carries the weight of some form of truth.

What our medical community needs to learn and practice, is to exercise consensus-decision making in view of the patient's best interest. Stakeholders need to be brought together, confronted and decide to collaborate, rather than to compromise. Achieving consensus requires serious treatment of every group's considered opinion until a convergent decision is developed. Such a process usually benefits from facilitation and requires understanding of the one-dimensional parameter space that is shaping the opinion of the surgeon, the interventional cardiologist or the patient's family member. Next, consensus failure in one dimension is replaced by a solution in a multi-dimensional parameter space that is both holistic and patient-centred. Accumulation of such consensus-driven decisions creates collective intelligence, defined\* as “the capacity of human communities to evolve towards higher order complexity and harmony, through such innovation mechanisms as differentiation and integration, competition and collaboration.” Overcoming individual cognitive bias and collectively cooperating on one process contributes to creating a so-called “noosphere” of public intelligence that distributes for the common good, a global brain, a group mind. “Collective intelligence restores control of the community over society and neutralises the power of vested interests that manipulate information to concentrate wealth.”

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Do these seemingly abstract concepts and theoretical approaches to consensus-decision making pertain to EuroPCR 2008?

Yes, very much so.

Is collective intelligence needed in our field?

Yes, more than ever.

Choices of revascularisation need to be weighed against the achievements of medical therapy. Secondary prevention has to be implemented more efficaciously in order to magnify the impact of revascularisation. Dual options for both percutaneous or surgical options have become available in many areas beyond coronary and peripheral atherosclerosis, including structural and valvular heart disease. Obligatory drug-device combinations for the longer term require a more holistic evaluation of patient's current – and expected – future needs.

Does one need to bring together various stakeholders?

Yes, more than ever.

EuroPCR has always been a global forum, inviting cardiologists, nurses and technicians but also colleagues from the industry and other specialists. EAPCI membership is inviting all those who are primarily interested in Percutaneous Cardiovascular Interventions, without consideration for race, culture, religion or... medical specialty! With more than 100 countries represented, parameters and metrics can only be multiple. A “one size fits all, top down” approach cannot be right.

Now the doors of EuroPCR have opened even wider.

The European Association for Cardiothoracic Surgery (EACTS) and the ESC Working Group for Cardiac Surgery have joined the organising team, such that surgery is now an integral part of the programme. Surgical therapy will be considered along with other options in virtually every session.

Is there any such “noosphere” building up during our meetings?

Yes of course, that is exactly why face-to-face meetings are still popular.

The knowledge base that is available on the internet is largely beyond what any single individual would need to know, or at least have access to. The refresh rate of this knowledge is so much better than was the case in the past, when relying on our favourite textbook. However, sharing skills and grasping consensus-driven decision making are less easily achieved in isolation, while sitting in front of the computer screen.

The programme of EuroPCR Barcelona 2008 offers us many opportunities to acquire this experience, for the best interest of our patients and their families.

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\* Most of the definitions and considerations regarding “consensus” included in this editorial can be found on ... the internet (see Wikipedia).

## A visible role for EAPCI at ESC Annual Congress 2008

William Wijns<sup>1\*</sup>, MD, PhD, FESC, President EAPCI

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People are always saying that there are too many congresses in every branch of medicine and perhaps this is true, all the more reason that the European Association of Percutaneous Cardiovascular Interventions (EAPCI), which is not in favour of excess, plays an active role in ensuring what does exist is of the greatest value to those attending. The EAPCI supports and endorses the scientific sessions of the various national interventional cardiology groups in different European countries, as well as specific meetings dedicated to fellows-in-training in interventional cardiology (a list is available on our website at [www.escardio.org/communities/EAPCI](http://www.escardio.org/communities/EAPCI)).

However, we play a different role in the annual subspecialty course on interventional cardiology which is EuroPCR, our official meeting as well at the annual congress of our mother society, the European Society of Cardiology (ESC). Here, our involvement is active and deep, shaping the essence of the meeting schedule itself. Having just returned from EuroPCR in Barcelona, we now turn our preparations to the ESC congress in Munich. Delegates from the EAPCI, who also sit on the scientific organising committee of the ESC congress directed by Fausto Pinto (chairman for the next 2 years), will soon begin the first steps towards 2009 congress preparation. Discussing how to insure that the ESC annual congress remains at the most exacting level of quality in its scientific medical and educational programme – a fact, witnessed by the increasing number of participants worldwide in this annual event. Obviously education and communication in our field is a continuous process and the EAPCI is playing an increasingly visible role.

We have highlighted below a number of sessions of particular interest at this year's ESC Munich annual meeting – with its emphasis on coronary imaging. Visit [www.escardio.org/CONGRESSES/ESC2008](http://www.escardio.org/CONGRESSES/ESC2008) for more information.

### Hot Line II: recently completed clinical trials in interventional cardiology

Monday 1 September, 11:00 - 12:30 – Room Munich, Zone A4

The Hot line Session II chaired by Prof. P. Widimsky and Dr. W. Wijns will be of particular interest for interventional cardiologists. The one year results of the SYNTAX (Synergy between Percutaneous Coronary Intervention and Cardiac Surgery) trial will be presented by the principal investigators of this 3,075 patient trial, the interventional cardiologist Prof. P.W. Serruys and the cardiac surgeon Prof. F.W. Mohr. Comparing CABG and PCI using drug eluting stents in patients with three-vessel and left main stem disease, the results will, hopefully, put years of debate between surgeons and interventionalists on a new footing, providing much awaited data on what is the best revascularisation treatment for patients with left main stem and multivessel disease.

In the same session other clinical trials will be presented:

- CARDIa, a randomised trial of bypass surgery versus angioplasty in diabetic patients, a 600 patient trial from the UK and Ireland, whose results complement SYNTAX, though on a smaller scale.
- LEADERS, the one year results of a study which is a randomised comparison of a biolimus-A9 eluting stent with a sirolimus-eluting stent in all-comers, without the strict inclusion criteria which have limited the applicability of the results of most DES studies to current clinical practice.

For those of you interested in hearing more information from the SYNTAX trial, you will have the opportunity to “Meet the Trialists” and interact directly with the presenters of this trial.

### ESC Andreas Gruentzig Lecture on Interventional Cardiology

Sunday 31 August, 14:00-15:30 – Rome - Zone C

This year's ESC Gruentzig lecture will be chaired by Prof. M. Tendera and Prof. M. Komajda. It will feature a presentation by Dr. R. Virmani on how preclinical biocompatibility studies in various animal models help predict human responses to intravascular devices.

Other sessions of interest include:

### Cardiac Anatomy for Interventional Cardiologists

Sunday 31 August, 10:00 - 12:30 – Cardiac Anatomy, Zone B4

### Association Track (Focus Session) – The best of EuroPCR08

Sunday 31 August, 08:30-10:00 – Room London, Zone B4

And new this year, an interactive Session on

### “Everything you always wanted to know about myocardial infarction and were afraid to ask”

Tuesday 2 September, 10:15 - 10:45 – Room Algiers, Zone C

### EAPCI General Assembly

Monday 1 September, 15:30 - 16:30 – Room 11, Level 1, Zone C

This will be the occasion for us to report on recent activities and new initiatives with special focus on interventional training, as well as the perfect opportunity for you to show your support and positive suggestions. The modalities for next year's election will also be announced.

To find out more about EAPCI, to learn about the EAPCI Membership Programme or gather information on next year's interventional fellowships, as well as on other sessions of interest during the Munich meeting, please come and meet us at one of our stands, located in Zone B2 or at the ESC Membership Stand, Zone C or all year round at [www.escardio.org/communities/EAPCI](http://www.escardio.org/communities/EAPCI).

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## “Embargo” on scientific news, a late breaking message from the Ministry of Truth (MiniTrue)

William Wijns, MD, PhD, President EAPCI

*Cardiovascular Center, Aalst, Belgium*

The word embargo comes from the Latin “imbaricare” and refers to the legal prohibition of trade, the movements of goods – or by extension – the diffusion of news and information. An embargo is considered as an act of “war” with the purpose of isolating one country or group from the other. As to scientific news, embargo results in the delayed release of new information until certain conditions have been met. The intention is that this scientific embargo will reduce inaccuracies in the reporting of the breaking stories. Unfortunately, the embargo system is considered as being primarily driven by profit motives on behalf of various stakeholders. It has indeed become obvious that different pressure groups have different objectives, often worthwhile ones. The industries need return on their investment; marketing experts are keen on maximising turnover (hidden gems are of little use!); analysts are under strong pressure to please their customers and make “true” predictions regarding the evolution of the market; congress organisers are competing to craft the best possible program in order to attract as many delegates as possible; the various press bodies are looking for exclusivity, prime time releases or the “best selling” of (preferably bad) news; journal editors are obsessed by their impact factor and growth in readership.....and what about doctors? Doctors are influential, and all of the above mentioned pressure groups are trying (all too often successfully) to engage doctors in singing their song. While the professional and scientific community should care primarily (exclusively?) about progress in patient care, problems arise from conflict of interest issues as well as from the confusion of interest issues. Investigators may be sensitive to public exposure, better timeslots, wider exposure and therefore accept to delay data disclosure or select one forum rather than another for presentation of their results. Confusion of interest issues are even more difficult to deal with, that is when doctors are endorsing some of the above mentioned agendas, rather than living by one of the

essential duties expressed by the Hippocratic oath, namely the obligation to teach and share “know how” or any information that can be useful to patient’s well being.

“To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art – if they desire to learn it – without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken an oath according to the medical law, but no one else.”

The very reason why scientific meetings remain popular while all the information is basically available on the internet is because meetings provide unique opportunities for face-to-face interaction between peers, discussion of good and bad fortunes, the sharing of tips and tricks. These opportunities are now increasingly often jeopardised by disruptive embargo rules and regulations.

As far as true “Late Breaking Trials” or “Hot Line” communications are concerned, some form of embargo is surely appropriate, especially when dealing with pivotal studies on drugs or devices that are commercialised by publicly owned companies. Financial and stock market operations that could be illicit or raise ethical issues can be prevented or at least minimised by the embargo process. It should, however, be noted that some form of minimal communication, like issuing a press release mentioning that a given trial did or did not meet its primary endpoint, without disclosing exact figures, can be deemed necessary in order to avoid potential legal issues with corporate governance rules. Specific issues with regard to publication embargo on behalf of major medical journals are complex matters and these have been analysed in full length in many articles.

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The present editorial refers specifically to embargo restrictions that are now often increasingly imposed on nearly all forms of scientific communication at congresses, including reports on trial updates or even presentations of any type of study, in the absence of direct financial implications. These rules are promoting a number of skewed behaviours, particularly on the behalf of younger researchers who feel compelled to adhere to the restrictions that congress organisers or scientific societies seem to be capable of imposing on them. For instance, while the audience is expecting data disclosure, presenters will interrupt their presentation when it comes to the results slide. The attendees are then invited to attend the next meeting that will take place in Krottenburg or else, and the speaker usually explains such unacceptable behaviour by a statement like: "Our abstract has been accepted for presentation here or there and I am not allowed by the meeting organisers to disclose the results until then". I have even attended a presentation during which the speaker/scientist teased the audience with great, provocative results and eventually concluded that he could not show any data because he was filing a patent. Under these circumstances you really wonder why someone should be submitting an abstract at all: it is clear that the submitter never had a plan to present any data. This doctor has replaced scientific communication by marketing and advertisement, the ultimate example of what I call confusion of interest. Other examples of skewed behaviours pertain to trading between study sponsors, meeting organisers and investigator/presenters. If you decide to present at our meeting rather than at theirs, we will provide you with an extended slot, at the best time of the day, on the day with the largest attendance, etc...and all sorts of fishy deals or practices like these, more genuine to belly dancing than to the world of scientific discovery.

When it comes to "Hot Line" sessions, breaking an embargo is seen as a breach of trust and can result in sanctions. It should be noted that the three major cardiology societies (ACC, AHA and ESC) have attempted, but failed, to reach a global agreement. Indeed, they were not able to design a common policy with respect to rules, regulations and possible reactions in case of breaches. Late breaking communications at major US meetings have been taken off the program because of disclosure or leaks to the press, either intentional or accidental. The dispute between the American College of Cardiology and Dr. Martin Leon at the occasion of the alleged premature disclosure of the COURAGE trial has received massive attention on the internet (see for instance the relevant documentation on MedPage Today). The interested reader can find a detailed account of the events that led to the proposed disciplinary action and I will not comment on this, except by observing that current embargo rules at TCT conferences are probably the most stringent of all cardiology meetings, an illustration of the old French saying, "ce sont les braconniers qui font les meilleurs garde-chasse" (It is the poacher that makes the best game-warden). At the ESC, and certainly at EuroPCR, regulations are rather mild. Embargo rules are restricted to true "Late Breaking" communications, meaning the première public disclosure of major, clinically-relevant, randomised clinical trials.

So what would be a reasonable compromise between wild, irresponsible, possibly inaccurate communication versus excessive

embargo rules that only serve the war between various stakeholders for control of the information world?

From a clinical scientist's perspective, I consider free access to information as one of my fundamental human rights. Extension of embargo rules to virtually all forms of scientific communication, as we are witnessing, is totally unacceptable. It can be seen as yet another attempt at reducing professional leadership. When this trend is continued, it eventually implies loss of data ownership on behalf of any investigator. I see it as our collective duty to resist these pressures, no matter from which corner they are coming.

As a matter of fact, a reasonable compromise should be based on a number of simple, common sense rules. These can guide your decision to endorse or to... resist the embargo that anyone would like to impose on your freedom to communicate.

– Embargo rules should only be applied to true "Hot Line" or "Late Breaking Trial" presentations, exclusively for studies that have direct financial strings attached.

– Of course, scientific data should only be released when validated, robust, complete and thoroughly analysed.

– In this flat world, whether the data are first presented at this or the next meeting should depend exclusively on random effects, i.e. the first moment at which the study results become available, without consideration for geography, origin of the data, institution of the principal investigator or anything else.

– For sponsored studies, communication plans are discussed and agreed upon at the time of protocol implementation, making sure that the investigator's prerogatives are respected.

– Central to the physician's agenda is the patient's well being. Therefore, we shall not take part in manipulative communication of marketing plans, we will not show slide presentations prepared by the industry without being fully in control and understanding their content, we shall never agree to delay – let alone keeping under cover – valuable or relevant information. The latter is particularly compelling when a given product, device or drug under study is already available to doctors and patients.

### **Timing for 2009 EAPCI Elections**

EAPCI is preparing for its upcoming elections concerning the positions of President-Elect, Secretary and Treasurer for the terms 2009-2011.

Deadline for application to any of these positions is the 30th of January 2009.

All applications must be sent to A. Lafont, President of the Nominating Committee.

This event is crucial for the future of our association. These elections concern every member and in order to participate in the electoral process, you must join the EAPCI as soon as possible.

Applications for membership can be found on the website of the ESC: "[www.escardio.org/constituent\\_bodies/EAPCI](http://www.escardio.org/constituent_bodies/EAPCI)"

## As time goes on... reflections A greeting and ongoing wish-list from your EAPCI

**William Wijns, MD, PhD, President EAPCI**

*Cardiovascular Center, Aalst, Belgium*

Why is it that the course of time continues to accelerate: it is hard to believe, yet another year has past us by. Those celebrations heralding the advent of the new Millennium seemed like yesterday; do you realise that we are nearly done with the first decade of this new century!

I hope that you have all heeded the season's call for at least a moment of standing still, and have allowed that all too ephemeral slowdown in our hectic daily pace to charge your batteries again, permitting a fleeting moment of introspection and relaxation as well. I would like to take a second and look back on the first few years of EAPCI, sharing with you what might have been our achievements, as well as what remains to be pursued. My term as President will last for another short 9 months, still enough time to give birth...

By and large, the net outcome of our efforts has been more than positive. The overall objective of EAPCI, to become "the" exchange forum for all who care about cardiovascular health and wish to contribute to its improvement through the application of percutaneous interventions, remains an objective more desirable than ever before. What more needed, at the verge of a worldwide crisis, if not "a benevolent and representative organisation that seeks to synchronise efforts, contributes to consensus building, enhances sharing of experience, constructs bridges between (sub)specialties and stakeholders<sup>1</sup>." Some of the facts and figures listed below indicate that EAPCI is doing all of that, perhaps even beyond our expectations.

### Membership

EAPCI was created in August 2006 from the merger of an ESC Working Group and EuroPCR, under the umbrella of the European Society of Cardiology (ESC). To date, we count 1,828 members, mostly cardiologists, coming from 92 different countries on all continents. Top membership countries are Italy (156), Poland (117), Spain (114), United Kingdom (108) and Germany (105).

We have to work further on engaging non-cardiologists. It needs to be repeated that membership is open to ALL health care professionals for whom percutaneous cardiovascular intervention is the primary activity, including allied professions.

### Electronic communication

EAPCI has two websites offering specific information content and linked to each other. On the ESC portal, news from EAPCI can be found under "communities" and remains integrated in the global picture of mainstream cardiology. A variety of items can be found including professional news, information about congresses, deadlines for- and results of- grant applications, relevant documents and guidelines, newsletters. The ESC website averages 150,000 visitors per month, of which 100,000 are unique. Over 1,000,000 pages are viewed each month at <http://www.escardio.org/communities/EAPCI>.

The source for scientific and technical information is <http://www.europcronline.com>, largely but not exclusively derived from the knowledge base presented during EuroPCR congresses. To date, 4,523 PowerPoint lectures are available as well as numerous LIVE case demonstrations. Nearly one million sessions have been consulted (999,632!) and 4,216,585 PowerPoint lectures viewed.

### EuroIntervention journal

Our journal has grown to become a unique source of information, including a strong electronic content, appropriate for a rapidly moving field like ours. Manuscript disposal is now entirely computerised and 482 articles have been published, of which 582,352 pages have been viewed. The readership enjoys free access to the published articles as illustrated by the nearly 150,000 PDF downloads (precisely 149,507). Most importantly, EuroIntervention is now indexed in MedLine / PubMed (<http://www.eurointervention.org>).

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## EuroPCR annual course

Much has been said about our annual meeting. Suffice it to say that EuroPCR should now be recognised as having become the largest, worldwide meeting on cardiovascular interventions, with a critical focus on patient-centred issues and interdisciplinary cross-talk. New in 2009, the meeting program will include abstract-based presentations on clinical studies, scientific contributions on selected topics, or innovative technologies. Make sure to attend EuroPCR2009 in Barcelona, May 19th-22nd.

Looking back at these achievements gives us a rewarding feeling and tells me that all the efforts of so many were not in vain. But there is more to come and out of the many EAPCI-EuroPCR projects for the coming year, I would like to briefly share with you three that are very close to my heart.

1. EAPCI has launched an initiative called “Stent 4 Life”. The objective is obvious and most appropriate: PCI is life saving when applied timely by competent teams to patients presenting with acute coronary disease. EAPCI calls for action and will mobilise all your energy to promote this therapy, facilitate patient access, implement the guidelines, improve procedural success, thereby saving additional lives and restoring the perceived value of our work<sup>2</sup>.
2. The ESC Board has mandated a Task Force to prepare an update of the 2005 ESC Guidelines on PCI. The document is due to be finalised by mid 2010 and very importantly, it will be a joint Guideline on Revascularisation between the ESC and EACTS, the European Association of CardioThoracic Surgery. Again, together we achieve more...

3. EuroPCR has launched a sustainable project to support emerging countries in establishing self-supported interventional programs. SHARE, which stands for “Sustain Health Development in Africa through Responsible Education”, will help primarily through capacity building. We proudly rely on the full support of H.S.H. Prince Albert of Monaco, and the External Relations of the Principality. Needless to say, we trust that we will be able to call upon your contribution in this project as well.

With these stimulating projects in mind, I would like to close on a personal note. Season's greetings are about wishing families and friends all the best, a naïve if not foolish exercise, this time perhaps more than before. Personal happiness, good health are no foolish thoughts, they are indispensable to mankind's well being as are joy and happiness. But beyond wishful thinking, EAPCI is offering you opportunities to become even happier. Engage in our activities, share your knowledge, spread the consensus, demonstrate solidarity. There is no secret: only a good person can be truly happy, and only a good person can be a great doctor. EAPCI/EuroPCR is becoming an impressive construction, entirely built for the good, largely by unselfish volunteers. Let us work our way through 2009, bring our good stones to the EAPCI edifice, in the best common interest of our patients and our profession.

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## **“Stent 4 Life” Targeting PCI at all who will benefit the most**

### **A joint project between EAPCI, Euro-PCR, EUCOMED and the ESC Working Group on Acute Cardiac Care**

**Petr Widimsky<sup>1</sup>, Jean Fajadet<sup>2</sup>, Nicolas Danchin<sup>3</sup>, William Wijns<sup>4\*</sup>**

*1. Co-Chairman Stent 4 Life, ESC Practice Guidelines Committee, Cardiocenter, Charles University & University Hospital Kralovske Vinohrady, Prague, Czech Republic; 2. EAPCI and EuroPCR Board member, Clinique Pasteur, Toulouse, France; 3. Chairman of the ESC Working Group on Acute Cardiac Care, Hospital Européen Georges-Pompidou, Broussais-HEGP, Paris, France; 4. EAPCI President, Chairman of the ESC European Relations Committee, Cardiovascular Center, Aalst, Belgium*

### **Why “Stent 4 Life” ?**

Progress in pharmacological therapy and secondary prevention has improved the prognosis of patients with chronic, stable coronary artery disease (CAD). Indeed many previous trials as well as the recently published Courage study have confirmed that the natural course of coronary patients is generally good, with low annual mortality rates (< 2%). Being a chronic, slowly progressive disease with an inflammatory component, CAD is occasionally associated with increased risk and, eventually, poor outcomes at the time of acute, focal plaque events that result in intracoronary thrombosis. These unpredictable bursts can lead to sudden ischaemic cardiac death, myocardial infarction (STEMI) or unstable angina with a sharp increase in risk (>10% mortality rate) that will last for several months, until the disease enters again a period of a more stable course.

In patients with stable CAD, benefit of mechanical revascularisation using bypass surgery or stented angioplasty will be restricted to symptomatic improvement, unless a large proportion of the myocardium is at risk (10% or more) and can be revascularised. On the contrary, there is mounting evidence that myocardial revascularisation in patients presenting with acute forms of CAD is life saving: it reduces mortality, rates of non-fatal reinfarction and stroke, as compared to the previous standard of care (pharmacological treatment, including thrombolytic therapy for STEMI). This evidence has led all ESC as well as international Practice Guidelines to issue class I A recommendations for

revascularisation of STEMI, non-STEMI-acute coronary syndrome and other high-risk unstable angina subsets.<sup>1,2</sup>

As a result, common sense would dictate that resources are prioritised in order to target PCI to those patients presenting with the above mentioned disease subsets who will benefit the most from revascularisation therapies. While up to 85% of all PCI procedures performed in the United States in 2004 were still done to treat stable forms of chronic CAD, the practice has evolved and already today, treatment of acute coronary syndromes represents over 50% of the PCI case load in many European countries and abroad. Providing this service to the population is part of our essential responsibilities as a professional group and the public is entitled to expect this level of quality-of-care, across boundaries. At the same time, focusing human and financial resources on the treatment of acute coronary syndromes is rewarding from many perspectives: it provides tremendous added value to the practice of PCI, both for the public and the physicians, while health care payers will enjoy the high return on investment.

### **The reperfusion paradox**

Timely delivery of expert invasive revascularisation therapy to acutely sick patients is demanding and requires re-engineering of services. Although the superior safety and efficacy of PCI is acknowledged, many felt that reperfusion treatment using intravenous thrombolysis is more widely available, less dependent on geographic situation and existing facilities. The opposite is true: recent evaluation of practices

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across Europe shows that far more patients receive reperfusion treatment in countries with low use of thrombolysis and high use of PCI. With the help of representatives of the national interventional Working Groups and societies, EAPCI did conduct a survey of revascularisation strategies for acute CAD. Results of the questionnaire will be presented in detail during the upcoming EuroPCR meeting in Barcelona, 19-22 May 2009 and submitted for publication shortly. Some essential findings can be shared with the readers of this editorial. North, west and central European countries use primary PCI for majority of their STEMI patients. Pharmacological reperfusion in real life is not significantly faster than mechanical reperfusion, unless pre-hospital fibrinolysis can be delivered. Dominant use of in-hospital thrombolysis results in many patients being left without any form of reperfusion therapy. Mortality reduction by primary PCI is greater in real life than in randomised trials (except, it should be noted, in certain specific local settings, where a policy of fibrinolysis followed by systematic early PCI, has been shown to yield clinical results similar to those of primary PCI<sup>3</sup>).

Primary PCI rates over 600 per one million inhabitants would enable us to address the needs of most patients suffering from STEMI across Europe. Lastly, and perhaps most importantly, we have observed enormous variations in practice patterns. Particularly disturbing was the observation that a number of European countries / regions / cities seem to have (more than) the required capacity to effectively deliver primary PCI; yet it does not happen...

### What is “Stent 4 Life”?

Considering the indisputable scientific evidence on the one hand, and the inhomogeneity in existing practice patterns on the other hand resulting in tremendous inequalities in patient access to adequate care, we call for immediate action. The leadership of EuroPCR, EAPCI and ESC Working Group on Acute Cardiac Care is launching the “Stent 4 Life” initiative, in collaboration with EUCOMED, a global organisation that is representing our industrial partners. The mission of the “Stent 4 Life” coalition is to promote the lifesaving indications of PCI, implying that priority will be given to targeting invasive resources to those patient groups who will benefit the most. Rather than attempting to enforce top down directives, the program will rely entirely on national Interventional Working Groups and Societies. Synergy, rather than competition, with existing initiatives will be the goal. We are delighted that the National Infarct Angioplasty Project in the United Kingdom (290911/Treatment of heart attack national guidance, <http://www.orderline.dh.gov.uk>) has recently announced the launch of an ambitious project aimed at providing primary PCI across the country, starting with the creation of stakeholder networks.

Intrigued by the observation that a number of countries / regions seem to have succeeded in implementing primary PCI for nearly all patients in need, our first (ongoing) task has been to identify key facilitators and essential requirements for a successful program. Next, our project will

seek collaboration, involvement and ownership/participation of all interventional colleagues from EAPCI member states. Depending on the local status of PCI for acute CAD, and based on the results of the recent survey mentioned above, specific action plans will be designed. The “best practice” examples will hopefully be a source of inspiration to the less successful environments. The “Stent 4 Life” coalition will invest in selected countries through implementation programs, coupled with evaluation of the process as required. In selected regions / countries having unmet medical need in the optimal treatment of STEMI and NSTEMI, the program will attempt to improve medical practices by ensuring improved patient access to PCI as recommended by ESC guidelines.

In addition to these focused implementation programs that will be deployed in a limited number of areas, action will be taken across the EAPCI constituency, at all relevant levels: the profession, the public, and the political scene.

As you will realise while reading this article, we are extremely passionate about this endeavour. We trust that “Stent 4 Life” will mean a lot to you and even more to your many patients across Europe. We are convinced that this action will be of benefit to all. Engaging in “Stent 4 Life” simply is the right thing to do, and at this early stage, we trust and rely on the active involvement of the entire interventional community.

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## On the current epidemic outburst of meta-analytic rage in interventional cardiology

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Systematic reviews and meta-analyses have always been popular among clinicians and scientists, in part due to the appeal of a single scientific paper summarising all the available data on a specific topic. As shown in Figure 1, systematic reviews and meta-analyses have been performed more and more often in the last years within the field of interventional cardiology and applied to the assessment of potential advantages and drawbacks of many newly developed techniques, therapies and devices. The number of these meta-analyses that are published each year has however reached such incredible heights that, at this point, the outburst qualifies as an epidemic. Even though the authors of this editorial have contributed to some extent to this epidemic, they feel compelled to react to the developing meta-analytic rage in the cardiovascular literature.

In the past, it was not unusual that articles of this kind became seminal landmark documents which went on to influence clinical research and contribute to changes in practice. A good example is one that can be taken from the meta-analyses that demonstrated,

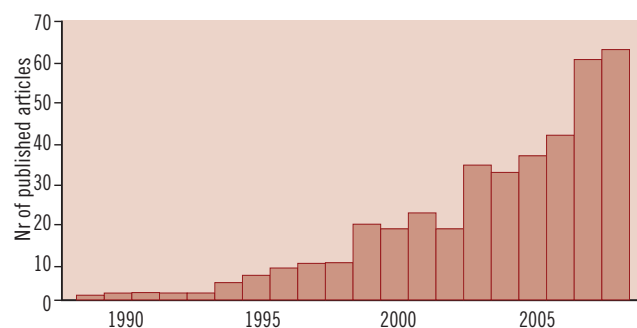


Figure 1. PubMed search (from 1985 to 2008) with the words: "meta-analysis AND percutaneous AND coronary".

very early on during the development of the therapy, of the advantages of primary percutaneous coronary intervention over thrombolytic therapy in acute ST segment elevation myocardial infarction<sup>1</sup>. Superiority of the invasive strategy became apparent, despite a huge difference in the number of studies that had been performed; very numerous large, industry-sponsored trials using different types of thrombolytic agents, as opposed to a small number of studies on primary percutaneous intervention, many of which were not powered to assess clinical outcome events and were often investigator-driven<sup>2</sup>.

Presently, the rapidly growing body of clinical studies and registries has stimulated the elaboration of several meta-analyses on various relevant clinical topics, often in the presence of original studies that are either few, small, inconclusive, or all of the above. This epidemic outburst of meta-analytic rage leads to the publication of numerous manuscripts, many of which only contribute to increasing the already long list of anonymous, never-quoted papers. In addition, we fear that the publication of poor quality, inappropriate, irrelevant or contradictory manuscripts will undermine the perceived, true value of meta-analyses, a type of investigation that should still be seen as providing the highest level of available evidence, when executed properly.

The holy grail of meta-analyses, similar to original work, should not be restricted to the "search for the p-value" that confers significant benefit of one type of treatment over another. Similar to original studies, meta-analyses are prone to errors and bias, dependent on the way they have been conducted and reported. We would like here to reflect on how to read and interpret meta-analyses, also keeping in mind that p-values are only one of the many results and conclusions that a meta-analysis can provide.

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## Definitions

Conventionally, a “meta-analysis” is performed after a systematic review of all data related to a specific clinical context has been completed. A “systematic review” provides an overview of all articles published in the literature focusing on a clinical problem<sup>3,4</sup>. The term “systematic” implies that all the steps underlying the review process are explicitly and clearly defined, and therefore could be reproduced independently by others, as desirable. In this process, a formal set of pre-specified methods is applied to: 1) study search (extensive search of the literature for original studies), 2) study selection, 3) study appraisal, and 4) data abstraction. The term “meta-analysis” is used to describe a statistical method that ends by pooling together results and data from several different original studies, to provide more precise and valid results (see Table 1 for further definitions). Thus, not all systematic reviews include a meta-analysis, as not all topics are suitable for sound and robust pooling of data. Sometimes, meta-analyses can be conducted outside the realm of a systematic review (usually they are called “pooled analyses”), without extensive and thorough literature searches, but then the results of the meta-analysis are best viewed as hypothesis-generating only. This is mainly the reason why meta-analyses, without a properly performed systematic review, entail a significant risk of bias.

**Table 1. Glossary of definitions.**

Term	Characteristics
Review	An overview on a subject, which quotes different original studies
Qualitative review	A review that avoids a systematic approach
Systematic review	A review that uses and reports a systematic and defined approach for search, selection, abstraction and appraisal of original studies
Meta-analysis	A study (not necessarily a review) which uses specific statistical methods for pooling data from separate original studies
Meta-regression	A study (not necessarily a review) that uses specific statistical methods for exploring interactions between dependent and independent variables from a meta-analysis dataset
Individual patient data meta-analysis	A study (not necessarily a review) that uses specific statistical methods for pooling data from separate original datasets using individual patient data

## Strength of meta-analyses

Systematic reviews and meta-analyses have several strengths<sup>3-5</sup>. They use systematic literature searches and compile the whole body of evidence on a particular question. The standardised processes for search, appraisal and selection of original studies allow reproducibility and objectivity. Thorough evaluation for internal validity and risk of bias in the individual original studies clearly identifies the limitations of these studies. Indeed, the greatest strength of systematic reviews is often their ability to pinpoint weaknesses and fallacies in apparently sound original studies<sup>6</sup>. Quantitative synthesis by means of meta-analysis also substantially increases statistical power and provides narrower confidence

intervals for statistical inferences. Assessing the effect of an intervention in different settings and at different times gives estimates and inferences of greater external validity. In addition, meta-analyses provide not only pooled estimates of effects, but also heterogeneity and inconsistency between included studies. Specific statistical analyses, such as the pooled estimates of effects, are an essential component of meta-analyses and should be reviewed critically. These parameters allow a critical appraisal of the overall quality of the meta-analysis, and also of the original studies included. They should always be reported and discussed by researchers performing a meta-analysis. Heterogeneity among original studies included in a meta-analysis is conventionally demonstrated by p values <0.10 at Cochrane Q heterogeneity  $\chi^2$  test<sup>7</sup>, while inconsistency among original studies is typically testified by  $I^2$  values >50%<sup>8</sup>. Clinical and statistical variability may be exploited by advanced statistical methods such as meta-regression, with the possibility of generating novel hypotheses<sup>9</sup>.

## Weaknesses of meta-analyses

Although meta-analyses are useful instruments of study, they cannot substitute appropriately sized and conducted randomised clinical trials<sup>3,10</sup>. While some authors believe that meta-analyses from homogeneous, randomised and controlled trials represent the apex of the evidence-based medicine pyramid, others have maintained that very large and simple randomised clinical trials should always be preferred, when available<sup>11,12</sup>. Indeed, meta-analytic pooling should be performed only if statistical homogeneity and consistency are confirmed, but this is not suitable when there is significant statistical heterogeneity or inconsistency. Conversely, a systematic and adequate appraisal of the potential reasons for this statistical variability can be justified. Additionally, small study bias is a major threat to the validity of meta-analyses<sup>3,10,12</sup>. Especially when datasets are large, small original studies are more likely to be reported, published and quoted if their results are significant. Conversely, small non-significant studies often fail to reach publication, and thus may be easily missed, even after thorough literature searches. Combining results from these ‘biased’ small studies with those of larger studies –which are usually published even when negative or non-significant– may inappropriately deviate summary effect estimates away from the true value. Although several graphical and analytical tests are available, small study publication bias is always potentially present in a meta-analyses and must not be forgotten<sup>13</sup>. Another major threat to the validity of a meta-analysis, as in any other research project, depends on conflicts of interest and how meta-analytical studies are funded. It is well known that reviewers with underlying financial conflicts of interest are more likely to draw conclusions that favour an intervention, which benefits the source of any financial gain<sup>14</sup>. These facts should encourage a more critical review of work performed by scientists with declared conflicts of interest. Needless to say, there are also more or less obvious conflicts of interest that are not openly declared by authors. In any case, the overall internal validity of the studies themselves, such as the blinding of patients, physicians, adjudicators and analysts, should always be evaluated. Finally, meta-analyses, as much as original studies, are prone to

statistical errors. Alpha error is defined as the risk of incorrectly dismissing a null hypothesis, despite it being true. Also, in meta-analyses, the risk of biased estimates and alpha error may be present<sup>3</sup>. Minor differences, in few and rare events, may give nominally significant results (with borderline significant p-values, for example  $p=0.04$ ) which, however, may not be reliable or clinically relevant. In any case, reliance on the combined appraisal of p-values and 95% confidence intervals is recommended. Another solution, is to use more stringent cut-off thresholds, such as 0.01 for p-values and 99% for confidence intervals. An additional, useful rule of thumb, is to trust meta-analyses reporting on at least 100 pooled events per group under comparison. The beta error is the risk of erroneously accepting a null hypothesis despite it being false. This error is also common in meta-analyses, especially when they include few studies with low event counts. This lack of sufficient statistical power (defined as 1-beta) is even more common with meta-regression analyses, which are usually underpowered because of the few studies included and regression to the mean phenomena<sup>15</sup>.

## Directions for the future

Systematic reviews and meta-analyses are powerful methodologies to assess the available evidence on a specific topic. However, their value mainly depends on the application of adequate methods and the quality of the individual studies that are included.

Prospective and well planned design is pivotal and offers a potential solution to avoid duplicate meta-analyses, at times providing opposite conclusions. It would be desirable to mandate registration of ongoing and planned meta-analyses, where topics, protocols and contributions can be made public, before the work actually starts. This same concept has been introduced successfully for original studies, whilst protocols are posted on dedicated freely accessible web-sites, such as [www.clinicaltrials.gov](http://www.clinicaltrials.gov), before beginning patient enrolment. Broader, collaborative, research efforts are needed to set-up international research groups able to design, conduct and disseminate individual patient data meta-analyses, which can combine results from individual clinical trials in an unbiased and rigorous way<sup>16</sup>.

The readership should be fully aware that the summing-up of several doubtful results only yields one big uncertainty. Even well conducted meta-analyses cannot repair the flaws of included studies when these are underpowered, or their data is poorly controlled or when they lack independent evaluation by professional core-laboratories and clinical research organisations. The inclusion of registry data in meta-analyses is highly questionable, because registry data can be tarnished by unrecoverable selection bias or unknown confounders<sup>17</sup> and meta-analyses aim at the analysis of the evidence that stems from randomised trials.

Based on these considerations, one can easily formulate a number of common sense recommendations that hopefully could be endorsed by the scientific community. The fundamentals pertain to the question of why and when a meta-analysis is needed and how it should be properly performed in accordance with well defined rules<sup>7,8</sup>. In many instances where the field is uncertain, uncertainty calls for an appropriate trial rather than for an inappropriate analysis of the existing, yet inconclusive data. Finally, it seems essential to bring an end to the wild dissemination of systematic analyses and

meta-analyses that do not comply with the above-mentioned recommendations. This calls for a thorough peer review process and consensus among journal editors. If not, the risk exists that the value of meta-analyses will be degraded due to the perception that they indeed no longer express the highest level of scientific evidence, but rather “manipulation” of this evidence instead.

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## Sustain Health development in Africa through Responsible Education (SHARE)



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1. SHARE Vice-President; 2. SHARE President; 3. SHARE General Secretary; 4. EAPCI President, Chairman of the ESC European Relations Committee; 5. Chairman of EuroPCR

In previous editions of our EAPCI column, we spoke briefly about the new SHARE-initiative, and now that the project is underway we would like to provide our members, along with the readership of this Journal, with further information.

### An obvious unmet need

As we all know, cardiovascular disease is the leading cause of mortality worldwide, accounting for 17.5 million deaths annually. Eighty per cent of these deaths and eighty-seven per cent of related disabilities occur in low and middle-income countries, many of which are faced with a double burden of disease – infectious and cardiovascular. The proportion of deaths due to cardiovascular disease is expected to continue rising in these countries, as their economies grow.

The African continent accounts for about 14% of the world's population. Africa offers the lowest output of cardiovascular research and needs more than just imported measures from more developed countries. Africa is in urgent need of medical education, administrative support and management skills.

Participation and involvement in associative initiatives has always been important to the members of the EuroPCR Board of Directors, several of whom independently are already involved in focal projects. The joint EuroPCR/EAPCI group decided that the time was right to consolidate these individual actions under the umbrella of an official structure, and that doing this was both logical and of great value. Concomitantly, Monaco's expertise and leadership across a number of successful humanitarian missions, along with the active encouragement by Monaco's highest official authorities led by His Highness the Prince Albert II of Monaco, have been critical in the creation of the association SHARE, officially registered in Monaco since October 2008.

### A joint initiative

SHARE stands for a joint Monaco/EuroPCR/EAPCI initiative to Sustain Health development in Africa through Responsible Education. Its mission is to contribute to the training and education of the entire medical team (medical, para-medical, administrative, financial, health providers, etc.) in selected sub-Saharan African countries, with the aim of developing local interventional cardiovascular units that will help reduce the burden of cardiovascular disease in both adults and children.

SHARE will review country projects that fit well with its mission, developing training programs for the expanded medical staff involved in the creation/development of a professional cathlab team. Additional items, identified as critical to the sustainability of the



H.S.H. Prince Albert of Monaco greeted by Jean Marco, EuroPCR, Barcelona 2008.

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project based on local conditions, will be duly supported by SHARE as well. Depending on the maturity of the projects we identify, this could lead us to anything from a two to five year, all the way up to a 10-year commitment for supportive actions. Needless to say, one has to be fully aware of the extensive involvement this project requires.

### **A best practice case example**

To provide more pragmatic insights, let's examine some of the details of our first project. In Nouakchott, Mauritania, at the Cheikh Zayed Hospital, a cardiovascular unit was created in 2003 at the initiative of François Bourlon, a French interventional cardiologist working in Monaco (and now Vice-President of SHARE). Originally, a team of Mauritanian professionals (cardiologists, cathlab nurses, technicians, managers and administrative staff) were identified and gathered together, whilst offered an adequate training and education plan over the following years. An on-going and continuous programme where the Mauritanian personnel are trained both in Europe and at home; in this particular instance, they receive training at Dr. Bourlon's institution by Dr Bourlon himself and his colleagues, or work at their own clinic in Nouakchott. François Bourlon and his associates have thus committed themselves also to regular educational visits to Nouakchott, with actual cases performed on-site. All necessary equipment and devices are now available there –SHARE can be of help in providing this as well– and the cases performed in Nouakchott have become instrumental in getting the programme started locally. Many patients, who have been diagnosed with cardiovascular disease, can now receive the most adequate treatment (including intervention) without having to travel to other countries – which was something they would have had to do before this SHARE programme began. The Mauritanian experience exemplifies the promise of this project, and truly fulfils the mission of SHARE.



*Starting left ventricular angiogram, supervised by François Bourlon, in the newly built cathlab at the Cheikh Zayed Hospital, Nouakchott, Mauritania.*

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We are at the infancy in the development of our association SHARE. We are ambitious and believe that the combined Monaco/EuroPCR/EAPCI expertise has set the proper basis for a thoughtful, ethical and respectful development over the coming years.

Beyond support by the Monaco authorities, we need and count on support, funds, contributions from the broader cardiovascular community, i.e., cathlab teams, hospital/institutions, industry partners. As we continue to evolve, developing our action plans, we will provide you with further details so that your support can be properly channelled. We trust that we can count on the active contribution of the interventional community in this endeavour.

Please send all requests for further information or questions to Patrick Jolly at [info@share-edu.com](mailto:info@share-edu.com).

## Notes on clubs and the forming of group identity

William Wijns\*, MD

*EAPCI President, Chairman of the ESC European Relations Committee*

In Cardiology, as much as in the outside world, we are witness to an explosion in the number of groups, societies, associations, congresses and clubs of all kinds to which people like to belong. From music to design, art to everyday life and current events, today, the creation of another social group, organisation or club appears commonplace. More than a fashion, more than a passing trend, it seems to be a part of our make-up as human beings, our need to belong to some exclusive, defining group. We, who have chosen to live in our “ivory tower” worlds of hospital and university, have made our own associative choice, and yet, nevertheless, we seem to be permeable to these changes and trends that are operative in the global society. Paradoxically, these centrifugal and insulated movements are blossoming at a time when information flows and transfers across walls with unsurpassed ease and speed.

### From our inside looking out

When we gaze on that outside world, indeed, without trying to voice any judgement or express any critique pro or con, it is remarkable to see a flat world whose borders are seemingly fluid, crossed all the time by the spread of information and communication, while at the same moment, we witness multiple examples of “repli identitaire”, meaning manifestations of introverted assertions of ones’ identity, clustering around language, cultural differences, socio-economic barriers, or simply interest groups of any kind. On the global scene, one has to admit that only seldomly does this introversion lead to something good, of course with the exception when its objectives are to liberate oppressed communities from any form of discrimination, as in liberation struggles. Otherwise, “repli identitaire” mostly leads to further isolation, lack of dialogue, degradation of the understanding between different communities, separatism, or sometimes even worse, when the other, the stranger is diabolised and made responsible for whatever goes wrong.

Europe can be seen as particularly vulnerable to such movements, since the only melting pot that can possibly consolidate the construction of a greater European Union is the desire of its citizens to work for a better common future - erasing borders, joining forces and wealth - despite the singular forces that keep pulling each constituent down to its original essence, which is precisely the motivation of the centrifugal forces, the fear of losing identity, the perception of being diluted, or even dissolved in a impersonal

magma. This mechanism has been excellently described by Amin Maalouf in “*Les identités meurtrières*” (English version; “In the Name of Identity: Violence and the Need to Belong”) on just how this can lead to wars and catastrophes of all kinds. The author of this editorial is exquisitely sensitive to these processes: living in Belgium, headquarters to most EU official bodies, at the crossroads of about every culture in the world, yet at the same time split (or threatening to further split) between two or three diverging identities, fortunately not (as yet) deadly.

### From the outside looking in

Is this reflection relevant to the world of interventional cardiology? I believe, very much so. Today we live our daily lives in the ivory tower of our hospitals, further divided into our departments that are more like fortresses within the hospital village. Specialities, now subspecialties, each are building their identity against the department, one hospital against the other, one international meeting vs the other, and so on. Interventional medicine is split between disciplines, the word is very appropriate: I only recently became aware of the fact that one “scientific” society has made bold enough to cancel the membership of their members in the event they actively take part in the meeting of the competing society. It is hard to believe that such a policy can be endorsed by responsible, intelligent people in the year 2009! Is this all nonsense, or is there some truth to be found in these movements. What about our discipline, specifically?

### Our crowd

We are indeed witnessing a similar fragmentation of efforts and initiatives, be it for research, meetings, and many of our other activities. One fascinating aspect of this is in the creation of “clubs” of all kinds: the European Bifurcation Club, the CTO club, the Club for Women’s Initiatives, the OCT Club, and who knows what else is on the way... Will we soon have the club of the right coronary artery? Or the club of the dominant left circumflex?

In my role as President of the EAPCI, a sort of club in its own right, I am not, by any means condemning the usefulness of these organisations/organisms, but rather trying to understand their mechanism, their original motivations and goals, hoping to clarify how to keep them valid and useful for the community.

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Reflecting on this, we begin with the idea that a club can be simply defined as an association of two or more people united by a common interest or goal. Service organisations or clubs, for example, exist for voluntary or charitable activities; there are clubs devoted to hobbies and sports, social activities clubs, political and religious clubs, and so forth.

So far so good. To be part of a group of like minded individuals, to debate and evolve together on common topics, all this is natural, the very creation of speciality organisations owes something to this natural propensity to come together with people who “speak the same language”. This common purpose, coming out of a challenge or joint experience can be seen as a positive movement using comparative equality to build on that experience towards a future goal.

But, as we have said earlier, there is a point when an invisible line is crossed, where we move into a nether realm where belonging to a group becomes the end in itself. A line that might be categorised as the point where synthetic development ends and a polarisation of attitudes and beliefs takes place, leading to a closing of dialogue. Where the people we can communicate with are all speaking the same, closed language of the group. And whilst we recognise the many positive aspects of “clubbing”, there is also the potential for a negative outcome.

One example from history is the Jacobin Club, which we might remember as the largest and most powerful of the political formations or clubs around the time of the French revolution. Evolving from a group of regional delegates in 1789 and initially moderate in nature, it fast grew in membership achieving both vast influence, and historic notoriety with its implementation and support of the Reign of Terror and condoning associated massacres. Its legacy today is in the use of the term “Jacobin” and “Jacobinism” as pejoratives for certain revolutionary or political activities.

For sure, none of the existing cardiology clubs begin to approach the boundless and extreme nature of the “Terreur”, but we should beware that excessive centrifugal evolution is potentially damaging, even for us, even in a perhaps, more docile fashion.

## Keeping the doors open

There is a feeling of camaraderie that cannot be denied, a need for belonging that is part of our species as a whole, which is not in and of itself an unhealthy phenomena, but when it becomes sclerotic, as it sometimes does, when we multiply our organisations, our clubs, to the point that we identify with them more than with solving the problems they were created to discuss, then we are in danger of entering a cul-de-sac. Evidence treated under these conditions is not fully evaluated, creative response to given problems is not received, if heard or understood at all. And this can happen subtly, over time, simply by the multiplication in our professional lives of groups we belong to.

We must be vigilant never to close off informed debate. To remain alert that our organisations that we belong to, formally or informally, continue to encourage an active and lively intercourse. We must not allow ourselves to believe that the only form of communications possible is with other members of the club itself – people like us, people who can understand us – but instead strive always towards a more universal goal in our discussions and experience, returning to

the initial reasons we formed our associations in the first place. In this respect, we can only be delighted that the dialogue with our surgical colleagues has been restored, testified, as well, by the official partnership with EACTS (European Association for CardioThoracic Surgery) that is now actively involved with the preparation of the programme of EuroPCR, the official annual meeting of EAPCI, and several other activities of our Association.

What would this ideal world look like?

I truly believe that there is benefit in gathering motivated people in small interest groups with the common objective of solving difficult problems, inventing new solutions to unmet needs, to serve the role of spurring on the larger, less flexible, less easily movable community. The example of the European Bifurcation Group is, to some degree, illustrative of that process. Dedicated interventionalists and clinical scientists are committed to advance the field of percutaneous treatment of bifurcation lesions. A broad representation from all European horizons are invited to join and to contribute. Progress is summarised in review articles or positions papers that are communicated to the public at large<sup>1,2,3</sup>. In this way the dialogue is maintained, the larger community benefits from the acquired expertise and the loop is closed.

However, the tasks and objectives of these groups should be clearly defined, the outcome should serve the larger community, and not solely the members of the elite. These founding rules could imply that there is both a time limit and a scope limit to the enterprise. These clubs should not become a structure in and of themselves, they are serving a given interest, and once satisfied, should either move to something else, possibly with different people, rather than aiming at becoming an entity of its own, inevitably competing with the official structures in terms of manpower, energy and resources. At a time of financial restrictions, sponsors themselves will most likely endorse similar views.

This article should not upset individual initiatives, it is by no means a call for uniform thinking, or the expression of a desire to control minds and behaviours, that would be an illusion in any case. Rather, this is a strong plea for not dissipating talent, energy and resources in a fragmented patchwork that will never reach the heights that can be explored when our forces are bundled.

Together we can truly achieve so much more ...

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## Presidential Criss-Cross The transfer of office between EAPCI presidents

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1. Onze Lieve Vrouw Ziekenhuis, Aalst, Belgium; 2. Royal Brompton Hospital, London, United Kingdom

On Monday, the 31<sup>st</sup> of August 2009, in a meeting (from 15:30 until 16:30) to be held during the European Society of Cardiology's (ESC) annual congress in Barcelona, the presidency of the European Association for Percutaneous Cardiovascular Interventions (EAPCI) will be handed over for the next two years to our newly elected Board under the leadership of Carlo Di Mario. It is thus, perhaps, the right moment for the future immediate past-president to reflect upon his term and for the future immediate past president-elect to share his plans with our members and readers.

### EAPCI: vision and achievements of the last three years

An overview of what EAPCI has achieved during its first three years of existence has been written about already in an earlier editorial<sup>1</sup>. Instead of claiming any merit, we would rather prefer to acknowledge that nothing would have happened without the vision of EuroPCR and ESC leadership, without the enthusiastic contributions of the many volunteers from the profession who are willing to donate their most precious gift, TIME, nor without the dedication and expertise of the staff at Heart House and Europa Organisation. We can proudly state that the leadership of both EAPCI and EuroPCR is constantly being broadened and rejuvenated, welcoming young colleagues from throughout greater Europe. The assets of EAPCI are well known: a great annual EuroPCR congress, a growing top quality EuroIntervention journal, two booming website portals... and yet all of these existed already.

What was the added value of joining forces, merging assets and linking our futures under the umbrella of the ESC and its Associations? In our mind, the added value stems from, at the very least, the following two aspects: First, within the interventional community, this coalition has initiated a new momentum, focusing and amplifying energy, fantasy, talent and enthusiasm for the sake

of reaching common objectives. Second, the interventional community no longer appears fragmented, opening up to mainstream cardiology, to other disciplines, to cardiac surgery in the first place – and perhaps to the public – in the future. The tendency of interventionalists to isolate themselves from the rest of the world, to live happily in a protected environment, to go on and on with the performance of self-referred procedures... no matter how fascinating and innovative these may be, this superb and arrogant isolationism was slowly but surely leading the field into a dead-end<sup>2</sup>. We think that the added value of EAPCI has been to confer structure, visibility, coherence to our community, leading EAPCI to become a representative body that can communicate, engage and dialogue with all partners and stakeholders<sup>3</sup>.

A proper structure is now in place, the processes are streamlined, the constituencies are engaged through the involvement of national interventional working groups and societies, we have a mission that reads loud and clear:

*"To reduce the burden of cardiovascular disease in Europe through percutaneous cardiovascular interventions."*

### Past new initiatives

New initiatives initiated during the last three years will be carried forward by the new Board.

The Stent for Life project was launched during EuroPCR 2009, the Call for Action will be officially endorsed during the ESC Congress and the project will then enter a critical phase of implementation<sup>4</sup>. The same holds true for SHARE, Sustain Health development in Africa through Responsible Education. This initiative is starting to deliver, contributing modest, but critical, building blocks to far reaching, locally-owned and locally-driven initiatives<sup>5</sup>.

At this stage, it is very appropriate for the soon-to-be EAPCI past-President to thank warm heartedly his Board; it was an honour and a personal enrichment to have the privilege to work with all of you:

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With the challenges ahead of all of us, it is obvious that the future will depend on the capacity of our community to focus on the essentials.

Of course, our main assets will be further nurtured. Stimulated by the difficult socio-economic environment, the Board and Programme Committee members of EuroPCR 2010 have begun preparing an ever innovative annual congress, capitalising on the return to Paris and the facilities of the Palais des Congrès, on May 25-28, 2010.

EAPCI is also looking forward to fresh initiatives and strategic changes to be spearheaded by our new leadership, in order to adapt to this changing environment.

### New challenges

What does the near future hold? Economic downturn means greater scrutiny of all public expenditures, with strict approval criteria for treatment generated by the net balance between efficacy and safety from an individual perspective posed against a favourable cost-effective matrix from the societal perspective.

At this stage, it is worth sharing with our members and readers a number of the important decisions that were recently taken by the ESC Board that will impact on the activities of ESC Associations, including ours. The objectives of the new EAPCI Board will develop along three main areas of interest: clinical research, registries and accreditation.

### Clinical trials

Interventional cardiology has produced massive amounts of data through large, well conducted randomised studies. In part, because the device and pharmaceutical industry has been the main and often sole sponsor for such trials, they have focused primarily on the evaluation of the technical performance of new devices or therapies, with less emphasis on comparisons with existing treatment. Non-clinical endpoints have often been used as surrogates for true clinically relevant adverse events. Facing reduced industry investment for research in Europe, we can no longer afford redundant efforts, underpowered designs, poorly funded studies due to duplicate initiatives, poor quality or biased analyses and inappropriate endpoint selection, thus providing conclusions unable to modify current guidelines and practice.

EAPCI and EuroPCR have implemented full disclosure of conflict of interests for all investigators submitting their results as abstracts or manuscripts, for abstract graders and manuscript reviewers, as well as for all speakers at our annual meeting. We are also actively involved in applying the conclusions of recent research trials to update the new joint ESC and EACTS Revascularisation Guidelines, due to be presented in September 2010. Still, we feel that we must go one step further, identifying critical questions regarding the progress and more widespread appraisal of interventional procedures. Proposals include the creation of a 'Think Tank' in the form of a dedicated EAPCI committee, in close cooperation with the brightest researchers Europe can offer. Its aim will be to ensure scientifically sound and clinically relevant choices for trial design, helping to secure funds from the European Community as well as individual governments, charities and industry partners. The potential of Europe for patient enrolment and acquisition of high quality data is curtailed by the increasing complexity of rules and regulations, differences from country to country, excessive overheads and failure to expand the pool of investigator sites to emerging areas. The potential of Europe for patient enrolment and acquisition of high quality data is curtailed by the increasing complexity of rules and regulations, differences from country to country, excessive overheads and failure to expand the pool of investigator sites to emerging areas. Here again, stay tuned, and you will hear more about this initiative from the 2009-2011 EAPCI Board.

### Registries

First, major changes are envisioned based on recent decisions of the ESC Board. The current structure of the Euro Heart Survey program, which presently includes a PCI Permanent Registry, will be substituted by a different structure whereby three ESC surveys will be conducted on a yearly basis, aimed at collecting representative data across Europe, with the support of national societies, working groups and associations. Proposed topics for 2010 are currently being evaluated by the ESC Board and the Euro Heart Survey Committee. EAPCI will strongly support the creation of a survey on Transcatheter Aortic Valve Implantations (TAVI) and proposes to take the lead in this effort, in collaboration with our surgical colleagues from the ESC Working Group in Cardiac Surgery and the European Association for Cardiothoracic Surgery (EACTS). Another important initiative to understand current utilisation as well as the results of resources for the treatment of acute coronary syndromes is being conducted by the Working Group on Acute Cardiac care, led by Nicholas Danchin, in cooperation with our Association. All our members will be invited to actively contribute to a snapshot survey on acute coronary syndromes that will take place during one week, starting on December 7, 2009. The objective is to acquire data on all patients admitted with acute coronary syndromes across Europe, collecting data from emergency wards, coronary care units, general hospitalisation wards and of course, diagnostic and interventional catheterisation laboratories. You will hear more about this effort soon, and again, we would like to strongly encourage you to participate.

## Accreditation

Another important decision that was taken last January by the ESC Board pertains to the subject of accreditation and revalidation for general cardiology. ESC decided not to actively pursue a program of European accreditation and revalidation, fearing that this would inevitably create conflicts with National Healthcare Authorities and universities. The situation may be different for subspecialty training, since no nationally binding diplomas or certificates are available<sup>6,7</sup>. EAPCI has already contributed significantly to the preparation of an accreditation process for trainees in interventional cardiology by developing a specific curriculum and syllabus<sup>8</sup>. Thanks to the stimulus provided by EAPCI, didactic fellows courses are now organised on a yearly basis, and a wide spectrum of educational events is offered to Fellows-in-Training during the EuroPCR congress and on our web-sites. In this way, EAPCI and EuroPCR aim to provide ample opportunities for acquiring the knowledge, skills and professionalism that are required from a properly trained European interventional cardiologist.

## Final remarks

It is appropriate for the incoming EAPCI President to welcome the team who will help him to face these challenges. We have decided to increase the involvement of national interventional working groups and societies. They have been formally requested to provide names and proposals for the future Committees which form the backbone of our Association. The committee structures will be announced during the EAPCI General Assembly on August 31, 2009 (from 15:30 till 16:30). Make sure to mark your calendar and to join the family. We are looking forward to meeting all of you once again at the ESC Annual Congress 2009 in Barcelona.

## EXECUTIVE EAPCI BOARD 2009-2011

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