

# Barriers to cardiovascular device innovation in Europe

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## Introduction

Innovation has played a significant role in the dramatic reduction in mortality due to cardiovascular disease (CVD). Despite this, CVD remains the leading cause of death in Europe, claiming 4.3 million lives each year at an annual cost to the region's economy estimated at €200 billion.<sup>1</sup> Now, two worrying trends are emerging that have profound consequences for the continuing fight against CVD: the significant increase in the very elderly population<sup>2</sup> and a steep rise in the incidence of metabolic disorders such as obesity and diabetes. Forecasts suggest that, by 2030, CVD could affect up to 40% of the population.<sup>3</sup>

These trends are likely to translate into a dramatic increase in patient numbers, demand for more effective treatments, and increased pressure on budgets already under intense scrutiny. To respond effectively to this situation, cardiologists have recognized the urgent need for a next generation of cardiovascular treatments and devices. Innovation will have to be focused on pioneering new techniques which allow faster delivery of effective therapies to all patients in need, reduced duration of hospitalization and recovery, fewer re-admissions, improved quality of life, and overall value-for-money.

Given the major challenge to cardiovascular health in Europe posed by these adverse trends—as well as the rapidly accelerating cost of healthcare—the argument to address the need is compelling. Yet the Cardiovascular Round Table (CRT) believes that a major element of the innovation process is under threat from declining investment.

Device manufacturers are concerned that their ability to invest in future research and development R&D programmes will be limited by the unintentional side-effect of inefficient processes within reimbursement models. Over the last 10 years, EU countries have utilized a wide range of reimbursement and funding models which

include the diagnosis-related group (DRG) system, fee-for-service, global budget, and devices positive lists. The most widely used of these in Europe is DRG, although the extent of implementation differs from country to country. Most reimbursement models establish *de facto* national rate cards for in-hospital treatment and, to qualify for reimbursement, individual procedures have to be allocated a formal code and associated tariff.

Manufacturers are already reporting a significant shortfall in the forecast utilization of the current generation of cardiovascular devices even when there is a stated demand, regulatory approval has been obtained, clinical efficacy has been proven, and the techniques are included within formal guidelines. This assertion is supported by independent research which demonstrates a clear correlation between utilization rates for the transcatheter aortic valve implantation (TAVI) procedure across Europe and the reimbursement strategy adopted by individual countries.<sup>4</sup> In certain countries, the process of allocating a code following CE Mark award delayed market access by 6 years.<sup>4</sup>

Reasons for delays are not clear, but may be linked to pressure on healthcare budgets and the availability of skilled people. While a small number of countries have interim processes in place under which promising procedures can be appropriately reimbursed pending the award of a formal code or status, these are not widespread, often lead to inconsistent recourse, and lack transparency and predictability. When added to a complex R&D lifecycle and intensive regulatory activities, the cumulative effect is unpredictable and inconsistent demand. Patients are suffering from reduced and delayed adoption of effective therapies, while poor return-on-investment (ROI) and revenue streams are forcing companies to scale back R&D programmes in the next generation of cardiovascular devices.

By highlighting these issues, the Cardiovascular Round Table invites stakeholders to urgently consider how to avert the threat to future

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innovation in cardiovascular devices and provide cardiologists with the treatment technologies needed to continue the fight against CVD.

## Background

While celebrating increased life expectancy, the CRT notes that the rapidly ageing European population has many long-term implications for healthcare and social budgets. By 2050, the number of people over 50 will rise by 35% and over 85 by 300%.<sup>2</sup> As the most prevalent forms of CVD are degenerative, the implications are significant. In terms of the cardiometabolic epidemic, including diabetes and obesity, the CRT believes that preventive measures and patient education are the best approach, but it also recognizes that cardiologists need to prepare for the impact.

If Europe continues to mirror the USA, 40% of its population will have at least one form of CVD by 2030,<sup>3</sup> while 50 million adults in the EU currently have diabetes with estimates showing an increase to 64 million by 2030<sup>5</sup>—and two-thirds of these can expect to die from heart disease or stroke.<sup>6</sup> Globally, while 10% of adults are classified as obese with a measured BMI of 30 kg/m<sup>2</sup> or more,<sup>7</sup> the rate in some European countries is well over 20%.<sup>8</sup> The incidence of atherosclerosis-related CVD is expected to accelerate and adverse lifestyle factors such as lack of exercise, high-fat, and sugar diets, and alcohol and tobacco consumption continue to present major risks, especially in the younger population.

According to the WHO, CVD and diabetes accounted for over 50% of all global deaths from non-communicable diseases worldwide in 2008 and 30% of all deaths,<sup>9</sup> while the global cost of treatment by 2030 for CVD and diabetes is estimated at a staggering \$1.8 trillion.<sup>9</sup>

## The innovation process

Innovation is a fundamental component of increased life expectancy, particularly in cardiovascular techniques and devices. US data show that 25% of the reduction in the age-adjusted death rate per 100 000 from CVD over the period 1980–2000 is due to improved treatment modalities.<sup>10</sup> Other authors have also demonstrated a clear correlation between declining death rates from CVD and the introduction of innovative new techniques and devices.<sup>11</sup>

In general, the innovation process for cardiovascular devices can be conveniently separated between the primary research phase and the development phase. Promising academic research programmes typically result in the identification and prototyping of new treatment techniques, often with a contribution from medical device companies that provide specific expertise as and when required. Taking the concept through development to final product, however, can only be accomplished with a handover to industry partners that have the necessary skills and financial resources.

The complete end-to-end development programme for cardiovascular devices is a major undertaking. The cumulative time to achieve market access is dominated by regulatory and reimbursement approval, and the conduct of clinical trials. These issues are factored into strategic planning assumptions and ultimately the programme costs and risks are weighed against the size of the opportunity and its value.

Market access for new devices is a major challenge. In 2011, the ESC emphasized the importance of considering transparency, safety, and clinical efficacy when making the decision.<sup>12</sup> In 2012, the European Commission issued its proposals for revision of the Medical Devices Directive regulations.<sup>13</sup> The ESC broadly welcomed these proposals while stressing the need for quality control and increased post-market surveillance.<sup>14</sup>

From the perspective of manufacturers, the need for complex submissions to multiple bodies has made it harder to justify business cases for cardiovascular devices in recent years. It is, of course, crucial to demonstrate safety and clinical efficacy, and industry also accepts that it has to demonstrate value and prove cost-effectiveness in order to address concerns over rising health expenditure. However, because there is currently a lack of transparency, consistency, and predictability across European healthcare systems, there is no certainty that such steps will lead to timely approval or adequate reimbursement.

## The innovation challenge

There is no suggestion that individual countries are deliberately delaying the allocation of reimbursement codes to, in effect, ration new and expensive treatments. It is more likely that cutbacks and budgetary pressures have resulted in less staff available to undertake the necessary analysis in a timely fashion. It may seem surprising that administrative inefficiencies in the reimbursement process could have such a profound effect on the development of new cardiovascular devices, yet the warning signs are clear. Cardiovascular Round Table members are already reporting that future R&D budgets are under review as companies face poor ROI from the current generation of cardiovascular devices. This situation has worrying implications, and raises concerns whether there can be an effective response to the demographic and cardiometabolic trends.

Not all reimbursement models have a fit-for-purpose and efficient process under which new treatments and procedures are incorporated. Even when there is a process in place, it is often difficult to determine the progress of utilization, performance, and cost analysis. Ideally there should be a transparent process involving all stakeholders, in which data are accurately analysed in a timely manner and made available to those that need it. This would allow a new procedure to be rapidly awarded an appropriate code if analysis supports such a move. The procedure can then be performed routinely with hospitals free to develop capabilities to offer it, confident that their costs will be fully reimbursed. This, however, is not the case for the majority of countries.

It is important to emphasize that the starting point of the process to allocate a code is the CE Mark award which confirms patient safety and demonstrates the effective performance of the device as defined by the manufacturer. The process should then be based around the analysis of utilization and performance across a representative number of centres and the capture of cost data from a representative number of procedures. Allocating a reimbursement code at national level, therefore, is an administrative step rather than a clinical step, yet experience shows that it can take 6 years or more<sup>4</sup> to complete.

Let us consider the example of TAVI. Transcatheter aortic valve implantation is an innovative technique developed to treat patients

with severe symptomatic aortic stenosis that are either ineligible or at high risk from surgical aortic valve replacement (SAVR).<sup>15</sup> Transcatheter aortic valve implantation was granted a CE Mark in 2006. Recent research analysed the prevalence of aortic stenosis and estimated the potential TAVI candidate pool at 190 000 in Europe, growing at 18 000 per annum.<sup>16</sup> Further research then determined that those countries which have already agreed an appropriate reimbursement value for TAVI conduct the highest number of procedures while countries which have not yet allocated a specific code (and instead continue to reimburse according to the SAVR code) conduct the lowest number of procedures.

In financial terms, the reimbursement value of TAVI in Germany is around €33 000 compared with €22 000 for SAVR.<sup>17</sup> The additional cost reflects the complexity of the procedure so, in those countries which are still using the SAVR code, this would translate as a significant reimbursement shortfall of around €11 000 per patient. The CRT suggests that this could be a powerful deterrent to carry out the TAVI procedure even when the clinical case is compelling.

It would be foolish to state that the entire shortfall in TAVI penetration is a function of the reimbursement process, although they are strongly correlated. The inconsistency between countries is dramatic, with a 14 : 1 ratio of TAVI procedures per head of population performed in Germany compared with Ireland and Portugal.<sup>4</sup>

When it has been recognized that there is little risk to patient safety, some countries have established interim processes to provide temporary reimbursement codes for promising procedures. In Germany, for instance, hospitals can access an innovation fund that is set up and managed by health insurers to exploit innovative techniques that offer positive outcomes. In the case of TAVI, this was available within 1 year of the date of CE Mark award. It is disappointing that such interim processes are neither widespread nor consistent; however, when they are adopted, there is clear evidence that the tendency for under-utilization is significantly reduced.<sup>4</sup> In a recent paper looking at funding and reimbursement issues, Eucomed—the body representing the medical technology industry—strongly recommends that countries establish interim funds to support the adoption of new procedures pending the gathering of full cost and tariff evidence.<sup>18</sup> The ESC has supported the concept that reimbursement might be conditional on enrolling patients in registries<sup>14</sup> and, for TAVI, continued study is indicated to establish long-term durability and safety.

To reinforce the assertion that reimbursement systems are a potential threat to future cardiovascular innovation, it is helpful to consider two further examples:

*Percutaneous mitral valve repair (PMVR)* is a minimally invasive therapeutic option for patients with moderate-to-severe mitral valve regurgitation (MR) who are considered high risk for surgery. The condition is often associated with heart failure, one of the most common cardiac disorders worldwide. Patients with heart failure and severe or moderate-to-severe MR experience significantly lower survival rates than patients with heart failure without MR or with mild-to-moderate MR.

The benefits of PMVR include faster recovery, reduced hospitalization period, and improved quality of life.<sup>19</sup> Additionally, PMVR patients are less likely to require home care or nurse rehabilitation compared with conventional surgical valve repair patients. The MitraClip implant received a CE Mark in 2008 and its use has been

included in ESC Clinical Practice Guidelines since 2012. Randomized clinical trials have shown non-inferiority for major clinical outcomes compared with surgical mitral valve repair.<sup>19</sup>

Despite this, the PMVR procedure still does not have reimbursement approval in many European countries. Up to April 2014, 23 000 patients had received the MitraClip implant, substantially less than the anticipated candidate pool. Although there may be other reasons that contribute to the shortfall, the lack of reimbursement approval is a major factor. It may be the case that reimbursement of the PMVR procedure—and others in a similar situation—should be linked to enrolling patients in registries and trials to secure collection of more clinical evidence that would support adoption.

*Fractional flow reserve (FFR)* is a measurement technique which determines the severity of coronary artery disease with >90% accuracy, facilitating better decision-making and improving patient outcomes. Fractional flow reserve has become the reference standard for assessing the functional significance of intermediate coronary arterial stenoses, against which other promising methods are judged.

Clinical trials have demonstrated a near 30% reduced risk of death, myocardial infarction, and revascularization compared with angiography-guided PCI and an 86% decrease in unplanned hospitalization for urgent revascularization.<sup>20</sup> Basing decisions on FFR also avoids unnecessary stent procedures being carried out with a significant cost saving. Regulatory approval in Europe was granted in 1997, and the technique has been included in formal guidelines issued by, amongst others, the European Society of Cardiology, the American College of Cardiology, and the American Heart Association.

Despite the well-documented clinical and economic benefits of the FFR technique, appropriate funding and reimbursement of it still remains an issue of great concern. It took around 15 years for Germany and UK to update their DRG systems to allow hospitals to cover the costs of an FFR procedure while other countries are even further behind. In France and Belgium, for instance, physicians using FFR do not yet receive the appropriate fees, while reimbursement systems in Italy and Switzerland do not cover the procedure at all.

Fractional flow reserve is a compelling example of the paradox illustrated in this paper, that an innovative, fully approved procedure supported by a wealth of clinical and economic evidence is not available to patients across Europe due mostly to administrative obstacles. The consequence is inconsistent deployment of the FFR technology leading to poor patient outcomes and higher healthcare costs.

## Recommendations

In this paper, the CRT argues that an inefficient and inconsistent approach to allocating reimbursement codes poses a genuine threat to future cardiovascular innovation. There is anecdotal evidence that some companies are already cutting R&D budgets as a response to time-to-market delays and low adoption rates of important techniques such as TAVI, PMVR, and FFR. The CRT asserts that, as well as reviewing national processes for reimbursement approval, greater efforts should be made to implement interim and conditional funding models.

The CRT believes that the issues raised in this paper must be urgently addressed to create the conditions in which cardiovascular innovation can flourish and meet the challenges posed by adverse demographic and cardiometabolic trends. It is recommended that

- High-level consultation should be established between representatives of the EU, national regulatory authorities, medical professional societies such as the European Society of Cardiology, and industry trade associations to
  - Develop a methodology to determine how an integrated process for evaluating clinical evidence can be devised that streamlines scrutiny and enables more rapid clinical implementation of new devices after approval.
  - Establish and promote interim and conditional funding schemes for cardiovascular innovations.
  - Define entry criteria for promising technologies for interim funding consideration, ensuring that this is not used as a default position when immediate funding is more appropriate.
- National Cardiac Societies should monitor the progress of allocating reimbursement codes for significant new cardiovascular treatments by their respective health authorities and share the information across ESC member countries to establish a Europe-wide perspective of delays.
- The European Commission should establish target recommended timescales for the allocation of national-level reimbursement codes and undertake periodic benchmarking to determine progress against those timescales.
- The European Commission should develop guidelines and quality standards on conditional coverage schemes that will allow for synergies and predictability in national conditional coverage solutions across Europe, support further research into the concept of conditional coverage, and allocate funding from EU research programmes so that significant new cardiovascular treatments can be undertaken soon after the CE Mark has been awarded pending a full cost and tariff review.
- The European Society of Cardiology should further develop its EURObservational Research Programme as a platform to establish registries on innovative treatments, and analyse country-by-country adoption rates and safety and efficacy data.
- National Cardiac Societies should engage with their respective healthcare authorities in order to increase awareness of the issues raised in this paper.

**Conflict of interest:** The views expressed in this article represent a consensus of the authors and do not necessarily reflect the views of the organizations that employ, retain, or contract with the authors.

## Appendix: Cardiovascular Round Table member organizations

Abbot Vascular, Amgen, Astra Zeneca, Bayer Healthcare, Biotronik, Boehringer-Ingelheim, Bristol-Myers Squibb, Daiichi-Sankyo, Eli Lilly, GlaxoSmithKline, Medtronic, MSD, Novartis Pharma, Pfizer, Roche Diagnostics, Sanofi, Servier International, Siemens, St. Jude Medical, and Takeda Pharmaceuticals.

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## CARDIOVASCULAR FLASHLIGHT

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### Huge aneurysm of aortic right coronary sinus in an adult

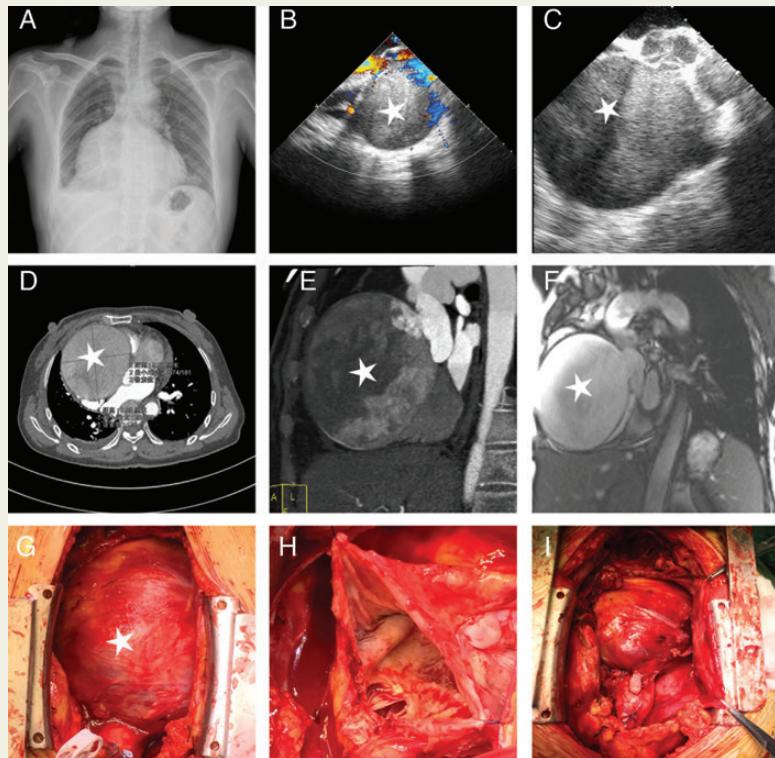
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A 52-year-old woman was presented to the emergency room with recurrent oedema of lower extremity for 1 year. Chest X-ray showed a convex contour of the right superior mediastinum (Panel A). The transthoracic echocardiography demonstrated that the huge mass was originating from the aortic right coronary sinus and mild aortic valve regurgitation (Panels B and C, asterisk; Supplementary material online, Movies S1 and S2). Computed tomography revealed the unruptured aneurysm of right aortic sinus (10 × 9.5 cm) and obviously deform and affect the right atrial and right ventricle (Panel D, asterisk). Magnetic resonance clarified that the echolucent mass was a huge aneurysm of aortic right coronary sinus without thrombus and showed the orifice connected to the right coronary sinus was about 2 cm (Panels E and F, asterisk; Supplementary material online, Movies S3 and S4). The patient received surgical intervention under the cardiopulmonary bypass. After pericardiotomy, the aneurysm was exposed and it filled almost all the pericardial cavity and compressed the right atrial and right ventricle (Panel G, asterisk). The aneurysm was identified originating from right coronary sinus and aortic valve is intact after incision of the aneurysm (Panel H, asterisk). The right coronary button was reimplanted to the aorta after reconstruction the orifice with a patch of pericardium and excision of aneurysmal body (Panel I). The patient recovered uneventfully and discharged 9 days later.



Supplementary material is available at *European Heart Journal* online.

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