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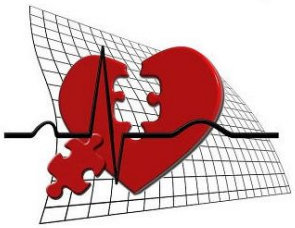
Patient Access to Cardiovascular Devices Delayed by Bureaucracy



Patients are experiencing significant delays in access to approved cardiovascular devices due to bureaucratic inefficiencies, reveals a Devices White Paper from the Cardiovascular Round Table (CRT) published today in European Heart Journal. There is a clear correlation between declining death rates from cardiovascular disease and the introduction of innovative techniques and devices. The CRT is an independent forum established by the European Society of Cardiology (ESC) and comprised of cardiologists and representatives of the pharmaceutical, device and equipment industries.

ESC President Professor Fausto Pinto, lead author and CRT member, said: “These devices are safe, approved by regulators and included in guidelines but inclusion in reimbursement systems lags behind. Patients may therefore have delayed access to recommended treatments because of bureaucratic delays. The knock-on effect is that return on investment is reduced and companies are scaling back R&D investment for future device therapies.”

He continued: “Innovation in cardiovascular devices is desperately needed to halt an epidemic of cardiovascular disease. Cardiovascular disease is the leading cause of death in Europe but an ageing population plus rapid growth of diabetes and obesity is pushing us towards an even greater problem. Research suggests that 40% of the population will have at least one form of cardiovascular disease by 2030. Novel devices are needed but inefficient DRG systems are putting development at risk.”

The authors state: “Device manufacturers are concerned that their ability to invest in future R&D programmes will be limited by the unintentional side effect of inefficient processes within DRG systems. Manufacturers are already reporting a significant shortfall in the forecast utilisation of the current generation of cardiovascular devices even when there is clear demand, regulatory approval has been obtained, clinical efficacy has been proven, and the techniques are included within formal guidelines.”

Under the diagnosis related group (DRG) system cases are categorised into diagnosis groups. Hospitals claim a standard tariff for each inpatient stay against the code for a treatment. When a new device is developed a code has to be raised so that it can be reimbursed. Prior to this, devices are awarded a CE Mark which certifies proven safety and performance. Individual countries then carry out a health technology assessment (HTA) which again evaluates safety and clinical effectiveness. Assigning a reimbursement code nationally should be purely an administrative step but can take six years or more.

The heterogeneity and need for repeated HTA assessment in various European countries could also represent another limiting step in the introduction of clinically proven technologies. “It is inefficiencies in allocating this code number for the current generation of cardiovascular devices that, surprisingly, represents a major threat to investment in the next generation,” warn the authors.

The paper provides examples of innovative device technologies that are underused due to inefficiencies in reimbursement, such as transcatheter aortic valve implantation (TAVI) and fractional flow reserve (FFR). The authors recommend ways to bring innovation to clinical practice sooner and make investment more attractive. These include:

- Establish a working group of EU and national regulatory authorities and HTA agencies, medical professional societies and industry trade associations to speed up clinical adoption of new devices after approval .
- National cardiac societies to engage with reimbursement agencies and HTA agencies to create target timescales for allocation of reimbursement codes and agree a process for interim funding of promising new techniques .

Professor Pinto said: “Research has shown a clear correlation between declining death rates from cardiovascular disease and the introduction of novel techniques and devices. However, reimbursement systems in Europe are blunting cardiovascular innovation. Now is the time for regulators, HTA agencies, professional societies, industry and national cardiac societies to speed up clinical adoption of new devices so that patients receive the best treatments now and in the future.”

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