

EDITOR'S CHOICE

Devices and desires

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In the wake of concern over breast implants and metal-on-metal hip replacements comes a warning about a new minimally invasive approach to aortic valve replacement. In this week's *BMJ* Hans Van Brabandt and colleagues argue that transcatheter aortic valve implantation (TAVI) "cannot be justified on medical or cost effectiveness grounds" (doi:10.1136/bmj.e4710). Since TAVI was introduced 10 years ago, there have been around 40 000 procedures worldwide. "But," say the authors, "serious unanswered questions remain over the clinical effectiveness of TAVI, as well as the regulatory process that enabled it to gain such a large market so rapidly, particularly in Europe."

So what are the risks? The authors cite evidence that the risk of mortality, stroke, or renal failure is increased in patients undergoing TAVI compared with conventional aortic valve replacement surgery. They say that, although there is a case for treating otherwise inoperable patients with the device, operable, low risk patients are also having the procedure. The UK National Institute for Health and Clinical Excellence (NICE) has said that "for patients for whom surgery is suitable, albeit risky, the evidence for using TAVI was inadequate," and a health technology assessment by the Belgian government concluded that "Belgian health authorities should pay for TAVI in only a minority of patients (10%) of those currently considered for treatment." The authors present a rigorous analysis of available data and conclude that "the arguments supporting the widespread use of TAVI do not stand up to scrutiny."

So how did we get to this stage? The authors point the finger at the European regulatory system, explaining that medical devices—which fall outside the scope of the European Medicines Agency—"need only a simple quality certificate (CE

mark) to gain access to the market, putting them on the same footing as domestic appliances such as toasters." They say, "Europe's lax licensing laws set up in an era where medical devices typically comprised hearing aids, walking frames, and spectacles are not appropriate for implantable devices." They would like a requirement for "high quality randomised trials to show clinical efficacy and safety before granting marketing approval to innovative, high risk medical devices" and "a major improvement in transparency of information."

The Olympics may now be in full swing, but the spell of the opening ceremony—and in particular the sight of UK doctors and nurses jitterbugging around giant NHS beds—lingers. Who could forget the spectre of the Harry Potter villain Lord Voldemort looming over sick children? Was it all a sly reference to health secretary Andrew Lansley and his NHS reforms?

Whether or not this was a shameless piece of left wing propaganda, as some critics have claimed, many commentators agree that the NHS was one of the British achievements worth showcasing to the world, whatever the world may have made of it. But what do NHS staff make of the NHS as it enters yet another phase of change and uncertainty? John Appleby looks at some recent survey results and crunches the data (doi:10.1136/bmj.e5130). And, with several trusts now offering patients the choice of paying for their treatments and services (doi:10.1136/bmj.e5128), is the most basic tenet of the NHS—that it provides universal, equitable care free at the point of use—beginning to shift?

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