Metal-on-metal failures—in science, regulation, and policy

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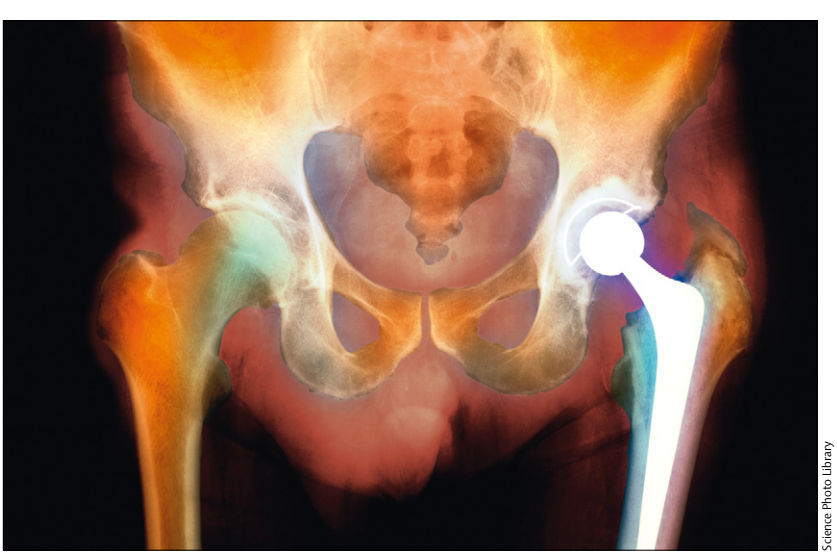
Worldwide there is dissatisfaction and fear among patients because commonly used implantable devices such as hip and breast implants, or defibrillator leads, fail. Metal-on-metal implants used for hip resurfacing or replacement are at the epicentre of the controversy because weaknesses in regulatory systems for medical devices have been exposed.[1,2] Initially the Australian and England and Wales registries reported failures associated with ASR (Articular Surface Replacement), a specific metal-on-metal device for hip replacement.[3,4] Subsequent reports highlighted common failures associated with large-head metal-on-metal implants in evidence from registries and comparative studies.[3,5,6] In *The Lancet*, Alison Smith and colleagues[7] now strengthen and extend the evidence that large-head metal-on-metal failure is not implant specific—it is a class effect. By use of data from the National Joint Registry of England and Wales, Smith and colleagues were able to assess more than 400 000 primary hip-replacement procedures, of which 31 171 employed stemmed metal-on-metal prostheses that were commonly used between 2003 and 2011. There was a 5-year revision rate of 6·2% (95% CI 5·8–6·6) in patients who had received metal-on-metal prostheses, substantially greater than that with other types of device and more elevated for prostheses with larger head sizes. Although the risk estimates are slightly smaller than those reported by the Australian Registry the follow up is also shorter within the National Joint Registry, which explains the difference.

How did surgeons, scientists, and regulators get here? There are three factors that have contributed to this dreadful situation: failures in regulation, science, and politics.

Outdated and low-threshold regulatory pathways such as the 510 (k) pathway in the USA or reviews of device reliability via notified bodies in Europe[8] have created an environment that makes regulators vulnerable to errors. The 510 (k) pathway only requires that substantial equivalency to another device on the market is shown—a predicate device. Moreover, the new device can then serve as a predicate for another device, and create a vicious cycle that could lead to approval of a new device that is very different from earlier predicate devices. Yet there are excellent hip implants on the market with almost no room for improvement.

The absence of robust post-marketing infrastructure is another and more important gap. The National Joint Registry of England and Wales, the world's largest registry, is not something that has been planned or funded by regulators. It is a voluntary reporting system that is nurtured by surgeons interested in improving their outcomes, with some support via an implant levy. There was a long struggle to make it national, with coverage now greater than 90%, and reporting is to become compulsory for NHS hospitals from April, 2012. Creating such a registry would be a much bigger challenge in the USA where fear of litigation, size, complexity of care, and identification problems are big hurdles to overcome. Absence of unique device identification codes makes the task nearly impossible to achieve without regulatory support, funding, and public–private partnerships. Innovative multinational efforts such as the International Consortium of Orthopaedic Registries[6] can help fill the gaps and reveal device problems early, but are not always a substitute for a high-quality national device registry with mandatory reporting and access.

Dominant scientific frameworks are also not supportive. A debate spanning more than a decade on the relative merits of randomised clinical trials and observational data[9,10] ignored the uniqueness of assessment required for surgery involving medical devices, and the cycle of evidence-based innovation.[11,12] In the USA, funding agencies such as the National



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Institutes of Health are interested in new discoveries and, until recently, not in infrastructure for comparative safety and effectiveness.[13] This practice fails to recognise that only a large national, or even worldwide, registry can address the needs when more than 10 000 products are on the market for the same purpose. National registries are part of the process and outcome improvement infrastructure that, when embraced by surgeons and clinicians, provides the most powerful and efficient method by which to advance the safety and effectiveness of medical devices. Moreover, a registry can be more evidence-based than the traditional framework of randomised controlled trials for care improvement. For example, in Sweden only five of 100 implants are revised after 10 years, showing the success of a more than 20-year-old registry effort. In the USA the revision rate is 2–3 times higher[14] and leads to more than a billion dollars in annual additional costs to taxpayers.

The UK's Medicines and Healthcare products Regulatory Agency and the US Food and Drug Administration are under pressure to ensure device safety, but in the USA there is also substantial pressure from Congress not to stifle innovation and to undertake faster reviews.[15] Asking for less burdensome and shorter reviews from regulators contributes to the availability of tens of thousands of so-called innovative hip-device components in the USA, compared with about 150 devices in the UK and only six best performing devices in Sweden. It would not be surprising if metal-on-metal hip prostheses were just the tip of a device-safety iceberg yet to be revealed.

Policy makers need to appreciate that registry data alone are not a substitute for good premarketing studies, which should include testing of implants.[6] When failures take a long time to develop, many faulty products can enter the market. In the case of the ASR and metal-on-metal implants it took 4–5 years before evidence was accumulated and reported. We are left with more than 500 000 patients with metal-on-metal prostheses in the USA and more than 40 000 in the UK who are at elevated risk of device failure, which will inevitably result in the burden of further surgical treatment as well as billions of dollars in costs to taxpayers.

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I declare that I have no conflicts of interest.

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