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- Editor's Choice

The trouble with medical devices

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In 1993 a *BMJ* editorial warned of the “fashion trade” in joint replacements (*BMJ* 1993;306:732). It said this was costing health services many millions of pounds each year and causing patients pain and distress through early failure of unproved implants. This week an investigation by the *BMJ* and Channel 4 *Dispatches* shows how right this view was and how little has changed.

As Deborah Cohen describes (doi:10.1136/bmj.d2905), one particular “metal on metal” hip implant has been used in more than 93 000 patients since its approval in Europe in 2003. It was withdrawn last year. In the intervening years, the manufacturer ignored concerns raised by surgeons and registries about its high rate of failure and high concentrations of metal ions in patients’ blood. The device didn’t make it past some regulators outside Europe where safety checks are more demanding. But until it was forced to acknowledge the damage to patients, the UK regulator did nothing.

The story makes uncomfortable reading. It shows how poorly we evaluate and regulate medical devices (doi:10.1136/bmj.d2748). It shows the flaws in a system that, as Nick Freemantle comments (doi:10.1136/bmj.d2839), might be ok for toasters and kettles but is completely inadequate for treatments that affect patients’ quality of life and can cause their death. It also shows, as Matthew Thompson and colleagues describe, the lack of transparency over what tests are done before a device is approved (doi:10.1136/bmj.d2973). A recent study in the United States analysed data on devices recalled from the market. In their study just published in *BMJ Open* (http://bmjopen.bmj.com/content/early/2011/05/12/bmjopen-2011-000155.abstract), Thompson and colleagues tried to replicate the study in the UK. They found it impossible. The US Food and Drug Administration publishes a list of devices on the market and says what regulatory processes these had passed through. No such information is available from the UK’s Medicines and Healthcare products Regulatory Agency. The Freedom of Information Act is trumped by laws that protect commercial confidentiality.

This story also forces us to confront the extent to which surgeons are entangled with device manufacturers. As Peter Wilmshurst says in his editorial, if we thought competing interests were a problem in drug prescribing, their effect on medical devices is far worse (doi:10.1136/bmj.d2822). Are these close relations inevitable? Surgeons’ technical skill and experience are essential to the iterative development of devices. How should they manage their relations with device companies? Should they be involved in evaluation? Should they be allowed to promote devices for which they hold shares and stock options?

John Skinner and Peter Kay explain what advice to give to patients with metal on metal hip implants (doi:10.1136/bmj.d3009). But what's to be done about the wider problem? Although C Di Mario and colleagues make the case against more regulation (doi:10.1136/bmj.d3021), it's clear that Europe's regulatory processes need urgent overhaul. Stefan James and colleagues say we need more and better registries collecting consecutive patient data (doi:10.1136/bmj.d2826), and Alan Fraser and colleagues call for international collaboration on clinical standards (doi:10.1136/bmj.d2952). They also say, and I agree, that the medical profession must accept some responsibility. "Too few physicians have taken an interest in the regulatory processes governing medical devices."

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