METAL-ON-METAL HIP IMPLANTS

Patients need to be informed about the evidence

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I agree that regulators and industry have to improve the regulation of medical devices, but Godlee implies that this will increase the evidence on effectiveness and safety and will lead to improved safety for patients.¹

Even if evidence on safety were available, there is a gap between knowing and informing or doing. Patients would still need to be informed by their clinicians to decide whether they wanted the metal-on-metal implant or the gold standard total hip implant. As recent media reports in the Netherlands, Denmark, and the UK on this “scandal” show, patients were not aware of the safety risk. But they could have been—information on the uncertainty of the evidence was available at the level of national Health Technology Assessment agencies, notified bodies, medical societies in Denmark and the UK, but it was not given to patients.

Whatever the level of evidence, patients need to be informed about it. Eucomed, which looks after the interests of the medical devices industry, once said that the level of uncertainty in evaluating medical devices may be greater than for other health technologies, and that more emphasis may be placed on value judgments. It is equally important to enable patients to state their preferences and include them in decision making. Patients should be informed on the evidence and the uncertainty around the evidence, so that they can state their preference. Tools, such as Annalisa (www.annalisa.org.uk), are available to support this kind of decision making. Currently, these tools are targeted at national bodies and clinicians, but an iPad or smart phone app that patients could take into the consultation room would force transparency on the harms and benefits of new and unproved health technologies.

Competing interests: None declared.

¹ Godlee F. Serious risks from metal-on-metal hip implants [Editor’s Choice]. BMJ 2012;344:e1539. (1 March.)

Cite this as: BMJ 2012;344:e2129

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