EDITOR'S CHOICE

Serious risks from metal-on-metal hip implants

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The recent scandal over breast implants has rightly focused minds on the safety and regulation of medical devices (*BMJ* 2012;344:e1460). This week a *BMJ/BBC Newsnight* investigation shines a forensic light on another group of widely used devices: metal-on-metal hip implants. But as Deborah Cohen says in her report (doi:10.1136/bmj.e1410), we're not talking here about "the unlucky failure to spot the misdemeanours of one rogue company or the occasional unforeseen breakdown of a small number of devices." This is a story of the collective and systematic failure of the regulatory-industrial complex.

Following on from her account of delay and commercial vested interest in relation to the now recalled DePuy ASR metal-on-metal hip implants (*BMJ* 2011;342:d2905), Cohen now describes how, over the past decade, manufacturers and regulators played down evidence that potentially carcinogenic and neurotoxic metal ions from implants were leaking into patients' tissues and blood. She also reports that design tweaks, intended to increase range of movement and reduce dislocation, were approved without clinical testing and have made the dangers of joint failure and ion leakage far worse. As a consumer advocate is quoted as saying, "This is one very large uncontrolled experiment exposing millions of patients to an unknown risk."

The *BMJ* strives to avoid being alarmist. Hip replacements are one of the great advances of modern medicine, and a link between metal-on-metal hips and cancer has not been proved. But what Cohen has uncovered is alarming. In a linked article (doi:10.1136/bmj.e1349), Carl Heneghan and colleagues remind us that cobalt poisoning was reported in the *BMJ* in 1967 (*BMJ* 1967;i:544-5), and that local tissue reactions associated with

ions from metal hips were first described in 1975. In 2000, NICE recommended that patients should be warned of the uncertainty about long term effects. Twelve years and globally millions of patients later, evidence on safety is still lacking. Published cohort studies have reported that occupational limits on ion levels are exceeded in a substantial proportion of patients and there is limited evidence of increased cancer mortality. A letter in the *BMJ* last month described five cases of cobaltism caused by metal-on-metal hips, variously comprising depression and anxiety, tinnitus, vertigo, hearing loss, cardiomyopathy, peripheral neuropathy, and endocrine disorders, as well as local tissue necrosis (*BMJ* 2012;344:e430).

At various stages both the manufacturers and the regulators had opportunities to call for a pause, request further research, put limits on the use of metal implants, or require routine monitoring of patients' ion levels. Repeatedly they failed to do so. Commercialism, medical vested interests, and regulatory inertia and overload all seem to have played a part.

What should doctors and patients do in light of these worrying developments? This week, in response to the *BMJ*'s investigation, the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) has issued emergency guidance on monitoring patients' ion levels (doi:10.1136/bmj.e1545). We hope regulators will also put limits on the use of metal-on-metal implants while more research is done, and, more fundamentally, that the pre-market and post-market approval of medical devices undergoes radical reform.

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