

One Million Surgical Guinea Pigs

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"Hundreds of thousands of patients around the world may have been exposed to toxic substances after being implanted with poorly regulated and potentially dangerous hip devices, a *BMJ* / BBC Newsnight investigation reveals this week. Despite the fact that these risks have been known and well-documented for decades, patients have been kept in the dark about their participation in what has effectively been a large, uncontrolled experiment."

The above is the opening paragraph from a recent [feature article](#) in the *British Medical Journal*.¹ In her article, investigations editor Deborah Cohen exposes how surgical device-maker greed was able to overshadow patient safety and regulatory oversight around the world for almost two decades. While much has been written about the dangers inherent in prescription and over-the-counter drugs, relatively little has been published to illustrate similar risks in surgery. This article is a must-read for every doctor of chiropractic to better understand the multiple risks inherent in all surgical procedures, particular those touted as innovative.

The devices in question are "metal-on-metal" orthopaedic surgical devices for hip replacement and resurfacing. In the United States, close to a million people have these metal-on-metal hip replacement / resurfacing devices. The author points out that the "average failure rates at seven years are 11.8% for resurfacing and 13.6% for metal-on-metal total hip replacement, although failure rates vary with the brand used. This compares with rates of 3.3%-4.9% for hip implants made of other materials."

These metal-on-metal devices are made with cobalt and chromium. In addition to the higher failure rates, they are known to release metal ions. According to Cohen, "these ions can seep into local tissue, causing reactions that destroy muscle and bone and [leave] some patients with long-term disability. Local tissue reactions associated with ions from metal-on-metal hips were first described in detail as long ago as 1975. The ions can also leach into the bloodstream, spreading to the lymph nodes, spleen, liver, and kidneys before being excreted in urine."

Further, the report states that "multiple studies and research organisations have warned about the carcinogenic potential of metal-on-metal hips. That cobalt and chromium ions lead to genotoxic changes both in laboratory settings and in animals was described in scientific journals over 30 years ago. Cobalt too was shown to be linked to cardiomyopathy in 1966. However, the link to cancer is not proved. In 1990, the World Health Organization International Agency for the Research on Cancer released a monograph listing hexavalent chromium as a proved carcinogen; trivalent chromium a potential carcinogen; and cobalt ions a probable carcinogen."

The device manufacturers have been aware of the potential for genotoxicity for years. The *BMJ* and BBC Newsnight reported seeing a July 2005 internal memo from metal-on-metal device-maker DePuy stating "In addition to inducing potential changes in immune function, there has been concern for some time that wear debris may be carcinogenic. The mechanism is not known and only 24 local malignancies have been reported in patients with joint replacements. Also worrying is the possibility of distant effects. One study suggested a threefold risk of lymphoma and leukaemia 10 years after joint replacement. The metal-to-metal total hip appears to be quite promising and in

the laboratory the data is ... definitely in its favour. However, the ultimate test is the long-term human experience."

Even with this level of uncertainty regarding potential patient harm, the marketing efforts for these devices continued and even escalated. The report quotes Nick Freemantle, professor of clinical epidemiology and biostatistics at University College London, who said, "If it was the pharmaceutical industry developing a new chemical entity, it would be abandoned early on if it metabolised in the wrong bits of the liver. We shouldn't be in this position where we don't know and there's so much uncertainty. The stability of a compound should have been ascertained before it was used widely in people. As yet, we don't know the consequences of this."

Sadly, regulators in the U.S., the United Kingdom and other countries failed to recognize the potential dangers of these metal-on-metal devices as opposed to previously cleared devices: "In the U.S., [the FDA](#) considered that the parts of metal-on-metal total hip replacements to be like other heads, cups, and stems already in use. This meant that the devices could be cleared through a less rigorous process, called 510(k), which requires no clinical studies to show how well these large heads worked when coupled with a modified stem."

In addition, even in the face of existing research, "the regulators mandated no post-approval studies requiring careful follow-up of patients implanted with devices capable of producing toxic debris. Instead, the only follow-up data came from ad-hoc studies by individual research teams."

As the author notes, "as competition grew the boundaries were pushed and the regulators were no match against the commercial pressure. Carefully crafted surgical innovations fell into the hands of the powerful multinationals and shareholder interests trumped patient safety."

The take-home message for patients is that while the marketing materials the medical doctors read will likely underplay the risks involved in surgical devices, many of the risks are likely not yet known. Just because the FDA has cleared a surgical device for use in humans doesn't make it safe.

Michael Carome, deputy director of the Public Citizen Health Research Group, is quoted in the article as stating, "This is one very large uncontrolled experiment exposing millions of patients to an unknown risk. We will only find out about the safety of these devices after large numbers of people have already been exposed."

Encourage your patients to read the report referenced below before they make any surgical decisions. It could save their lives.

Reference

1. Cohen D. "How Safe Are Metal-on-Metal Hip Implants?" *BMJ* ,2012;344:e1410:
www.bmj.com/content/344/bmj.e1410
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