More UK regulation of total hip replacement devices needed to prevent unnecessary surgery

March 10 2015, by Lee Page

A new study from the University of Warwick is calling for more UK compulsory regulation of devices used in hip replacements to reduce the need for further traumatic and expensive surgery.

In a paper published today in the *British Medical Journal*, a team from Warwick Medical School looked at ten year revision rates for five of the most commonly used hip replacement devices. This means the number of devices that had to be replaced within 10 years of the original surgery.

The team found the revision rates for these devices were less than 5% but warned many other devices still in active use had higher revision rates than 5%. As a result of the Warwick research, the National Institute for Health and Care Excellence (NICE) has now recommended a reduction in the benchmark for hip replacement revision rates from 10% at 10 years to 5% at 10 years.

One of the authors of the study, Professor Aileen Clarke said more regulation was needed and that revision surgery to replace a total hip replacement device was traumatic for the patient and expensive for the NHS.

She said: "When we undertook this research for NICE we found that the revision rates for five of the most commonly-used hip replacement devices were less than 5%, which gave NICE the confidence to suggest

this lower benchmark figure. This new guideline will help to make sure only the most effective devices are used, but the fact remains that the regulation process is not good enough.

"Whether a total hip replacement device is assessed by the Orthopaedic Data Evaluation Panel (ODEP) or not depends on voluntary submission of evidence from the device manufacturers. The assumption is that these devices can be afforded a looser regulatory mechanism than drugs but we question whether this is wise because it has allowed a large number of different brands of device to slip into routine use although some have high rates of revision."

Prof Clarke said that ODEP needed to be strengthened and that randomised controlled trials should be compulsory for devices, in the same way that they are for new drugs.

Fellow author Dr Ngianga-Bakwin Kandala said: "Past use of poor devices has been bad for patients, bad for the reputation of orthopaedics and of clinicians, and has contributed to a waste of NHS resources. The NICE guidelines are very necessary, but a poor second best to more effective and compulsory regulation."

The research team used data from the National Joint Registry containing records of primary surgery for hip resurfacing and total hip replacement between April 2003 and March 2012.

More information: "Setting benchmark revision rates for total hip replacement: analysis of registry evidence." *BMJ* 2015; 350 doi: dx.doi.org/10.1136/bmj.h756

Provided by University of Warwick