Inadequate regulation for vaginal mesh products has exposed women to unnecessary harms, warn experts

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Inadequate regulatory processes for vaginal mesh products used to treat stress incontinence and pelvic organ prolapse have exposed women to unnecessary harms, warn experts in *The BMJ* today.

Professor Carl Heneghan at Oxford University's Centre for Evidence Based Medicine and colleagues argue that regulatory failings have enabled new devices to be brought to market with inadequate evidence - and more than 100,000 women around the world are now suing manufacturers after developing serious complications.

What went wrong, they ask?

In the US, transvaginal meshes were initially class II devices (lower risk), allowing them to be marketed on the basis of equivalence to existing devices despite important changes, they explain.

So Professor Heneghan and his team traced marketing clearance for 61 mesh devices back through a chain of equivalence claims to only two unique originating devices approved in 1985 and 1996.

Their results, published in *BMJ Open*, show no evidence of any new clinical trial data at the time of device approval for all of these 61 devices, with empirical evidence of effectiveness from randomised trials emerging on average five years after approval (range 1 to 14 years).

They argue that changes in design "should have alerted regulators to important differences in the technological characteristics of the mesh that should have negated the use of equivalence."

They also show that evidence consistently pointed to a lack of long term data to inform use of vaginal mesh devices. And when longer term evidence did emerge, it identified serious concerns.

In recognition of the growing problems, many countries have already reclassified mesh as high risk, and NICE is recommending transvaginal mesh should not be used to treat vaginal prolapse because of safety concerns.

And new EU regulations, published in May 2017, mean that clinical investigations for class III and implantable medical devices will be required to provide evidence of safety and performance, explain the authors.

However, they point out that there is a three year transition period before these rules fully come into force, in May 2020. "We think these changes are insufficient, and the long delay in implementation does not represent a timely response to patients' needs," they write.

In the case of vaginal mesh devices, they argue that evidence from large pragmatic trials did not emerge until 20 years after the first products were introduced and 12 years after the call for longer term studies. "In our view, to be considered safe and approved for widespread use, long term implantable devices should have been evaluated in studies with follow-up of at least five years."

They suggest that limited access could be provided through temporary licences that restrict use to within clinical trials with long follow-up. "This would ensure that safety and effectiveness data were available before full marketing authorisation," they say.

They also recommend that a patient registry should be established for all implantable devices to enable

long term follow-up and surveillance. "Such registries should include unique device identification so that any shortcomings can be more readily tracked, patterns of use monitored, and patients later judged to be at risk more easily identified." they conclude.

More information: Carl J Heneghan et al. Trials of transvaginal mesh devices for pelvic organ prolapse: a systematic database review of the US FDA approval process, *BMJ Open* (2017). DOI: 10.1136/bmjopen-2017-017125

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