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LETTERS

SURGICAL MESH AND SAFETY

NICE responds to surgical mesh article

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The life changing complications that affect some women after vaginal mesh procedures should prompt us all to reflect on how the health system should monitor and respond to potential harms from any intervention, medicine, or device.

The National Institute for Health and Care Excellence first made recommendations about the use of mesh in its interventional procedures guidance in 2005.[1] This was cautious advice with requirements for notifying clinical governance leads, informing patients about uncertainties in the procedure's safety, and the need to audit outcomes. This advice is reinforced in our new draft clinical guideline on stress urinary incontinence and pelvic organ prolapse.[2]

In their editorial, Heneghan and Godlee refer to NICE guidance as "ineffectual,"[3] and we agree that it should have had more impact. Of course, responsibility for implementing guidance does not rest with NICE but requires a system-wide approach. A systematic approach after our recommendations in 2005 could have identified more quickly, or avoided, many of the adverse outcomes of mesh.

In future, the healthcare system should provide more robust implementation of all NICE guidance on interventional procedures, not just those relating to mesh. We should act on the requirements for implementing this guidance, endorsed by NHS policy makers from the four nations of the UK.[4] Interventional procedures guidance aims to protect the safety of patients, and its recommendations should be seen as mandatory rather than advisory.

Mechanisms to reinforce these recommendations include oversight by the regulator to ensure effective governance structures, and trust appraisal systems should ensure that clinicians take due account of our guidance. Clinicians should comply with requirements for consent, data collection, and audit, and should report complications.

Data submitted to national registers must be properly analysed and published to ensure that patterns of complications or harms are identified quickly. Coherent and coordinated action can then be taken where necessary to reduce future risks to patients.

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Full response at: https://www.bmj.com/content/363/bmj.k4231/rr.

1 NICE. Intramural urethral bulking procedures for stress urinary incontinence in women (IPG138). https://www.nice.org.uk/guidance/ipg138
2 NICE. Urinary incontinence (update) and pelvic organ prolapse in women: management. https://www.nice.org.uk/guidance/indevelopment/gid-ng10035/consultation/html-content-2
3 Heneghan C, Godlee F. Surgical mesh and patient safety. *BMJ* 2018;363:k4231. 10.1136/bmj.k4231 30305286
4 Health Service Circular. 2003/11.http://webarchive.nationalarchives.gov.uk/20120503190439/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4064925.pdf

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