Chief Medical Officer for Scotland

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The Scottish Government
Riaghaltas na h-Alba

Dear Colleague

REPORT OF THE TRANSVAGINAL MESH CASE RECORD REVIEW

Key points:

- The final report of the Transvaginal Mesh Case Record Review has been published. The Review found historic failings in respect of the consent processes that preceded some patients' treatments, and also inadequate or misleading recording of those consent processes and subsequent treatments.
- Health Board Mesh Accountable Officers have discussed the findings of the Review.
- **Medical Directors should seek assurance that measures are in place locally that prevent a recurrence of the failings identified in the report.**
- The measures set out in CMO (2018) 10 and CMO (2018) 12, concerning treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) continue to apply.
- Patients must be listened to, have their concerns taken seriously and have them acted upon appropriately.

Actions:

- Distribute this letter to relevant individuals.

From the Chief Medical Officer for Scotland
Professor Sir Gregor Smith

10 October 2023

SGHD/CMO(2023)18

Addresses

For action
NHS Scotland Health Board Medical Directors
Board Nominated Leads for Mesh

Further Enquiries to:

Medical Devices and Legislation Unit
First Floor Rear
St Andrew's House
EDINBURGH EH1 3DG

Dear colleague,

On 20 June the final report of the Transvaginal Mesh Case Record Review was published.

Professor Alison Britton and a panel of clinicians reviewed the patient records of a number of women who had concerns that their clinical records did not accurately reflect the treatment they had received while seeking mesh removal after experiencing complications. The Review found that patients also had concerns around flawed or inadequate consent processes at the time mesh was implanted.

The report focused on themes such as the importance of consent discussions and processes; the information given to patients to allow informed consent; and the importance of accurate recording of discussions with the patient, information given to the patient, decisions on treatment, and, where relevant, the recording of the procedure subsequently undertaken.

The report concluded in particular that, in many instances in relation to the records considered, there was a lack of clarity regarding the necessity of surgery, the outcome of 'conservative' treatments or, where relevant, an explanation of the risks and benefits of potentially undergoing mesh surgery. In a number of cases the Review Panel observed a lack of clarity in the case records documenting the nature and potential outcome of mesh revision surgery. Most alarmingly, the Review Panel concluded that some notes "did not bear any reflection to the surgery that had occurred, nor its outcomes".

I would strongly encourage any clinician involved in the mesh treatment pathway to read Professor Britton's report.

Health Board Mesh Accountable Officers have discussed Professor Britton's findings and have reported to Scottish Government officials that there are measures in place within the Complex Mesh Surgical Service (CMSS) in Glasgow and, more widely, in Health Boards, to prevent a recurrence of the failings identified in the Review. I am grateful to have received those assurances.

I would ask that **Medical Directors now take steps to satisfy themselves and their clinical governance committee chairs that measures in place are indeed sufficiently comprehensive and rigorous**, such that GMC guidance on decision making and consent and the principles of Realistic Medicine are conformed to in all cases.

I would also stress that all measures set out in CMO (2018) 10 and CMO (2018) 12 continue to apply. Nominated Accountable Officers in each Health Board remain responsible for ensuring that all requirements are adhered to, without exception.

I would lastly want to draw your attention again to the letter issued by my predecessor in February 2018 that stressed the importance of ensuring patients' concerns are listened to, taken seriously, and acted upon appropriately.

I would be grateful if you would ensure that this letter is distributed to appropriate clinicians and other relevant individuals within your Health Board area.

Yours sincerely

Gregor Smith

Professor Sir Gregor Smith
Chief Medical Officer