Chief Medical Officer and Public Health Directorate

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The Scottish Government
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Dear Colleague

TRANSVAGINAL MESH IMPLANTS

You will be aware of the announcement that an Independent Review is being set up to report on issues raised in relation to transvaginal synthetic mesh implants, specifically to consider complication rates and under reporting of adverse incidents from their use in the treatment of pelvic organ prolapse and stress urinary incontinence.

It is anticipated that this review will report early in 2015 and will take into account the findings of the Expert Panel set up by the European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) expected in January 2015.

I am writing to all Boards to request that they consider suspending the use of these synthetic mesh products in surgery for pelvic organ prolapse and stress urinary incontinence until this review is concluded and has reported.

In coming to any decision I expect Boards will wish to take into account the most up to date evidence of the effectiveness of the use of synthetic tape in the treatment of stress urinary incontinence and mesh in the treatment of pelvic organ prolapse compared to more traditional treatment options and other biological grafts. A good summary of the evidence is provided in the report from the York University Economics Consortium http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con205383.pdf

From the Acting Chief Medical Officer
Dr Aileen Keel CBE

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For information
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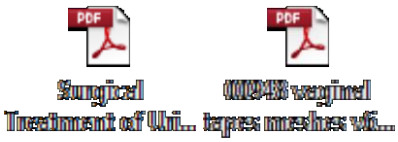
I understand women already on waiting lists for these procedures will be anxious as a result of this announcement and expect them to be offered the opportunity to discuss this with their consultant to allow them to review their decision in the light of evidence about the success and complication rates of alternative procedures. We expect that once women and their clinicians have considered the risks and benefits and decide to continue with surgery this should go ahead, taking into account the guidance sent out by my predecessor in December 2013.



If women are being considered for entry into clinical trials then use of mesh can be approved for women being entered into the arm(s) of the trial using this option. The Cabinet Secretary endorses this position.

For information I have also attached the new information and consent leaflet produced for treatment of stress urinary incontinence by the Working Group, including women affected by mesh complications, which should form the minimum content for your own information to women considering surgery.

I ask that once you have considered this request and made a decision about whether or not to suspend the use of mesh implants in either surgery for SUI or POP, or both, that you inform my office of the decision.

It would also be helpful if you could describe how adverse incidents relating to these implants are reported and how these reports are considered through your clinical governance committee.

Yours sincerely

Aileen Keel

DR AILEEN KEEL CBE