Directorate of Chief Medical Officer

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The Scottish Government
Riaghaltas na h-Alba

Dear Colleague

RESTRICTED USE PROTOCOL FOR INTERVENTIONS TO TREAT STRESS URINARY INCONTINENCE AND PELVIC ORGAN PROLAPSE

Further to my letter SGHD/CMO (2018)10, I now write to inform you of the actions I believe are required to further assure the treatment of women undergoing surgery for stress urinary incontinence (SUI) and pelvic organ prolapse (POP). This involves introduction of a **Restricted Use Protocol** with measures to ensure **high vigilance scrutiny**. The measures are broadly similar to those introduced in England and in the other devolved nations. They will apply to mesh and non-mesh treatments.

Procedures: level of restriction and scrutiny

The following list of procedures for consideration is under broad headings and indicates both the level of restriction and the degree of scrutiny that is required. The list is developed from SGHD/CMO (2018)10 and brief explanatory notes are added where additional clarity might be required.

- ***Tape procedures for SUI***

  All procedures subject of "halt" announced by Cabinet Secretary 12 September 2018.

- ***Mesh procedures for POP*** *(including pelvic floor repair/colporrhaphy)*

  All procedures subject of "halt" announced by Cabinet Secretary 12 September 2018.

- ***Abdominally-inserted mesh for pelvic organ prolapse (e.g. sacrocolpopexy, hysteropexy, rectopexy)***

  Not restricted; but subject to high vigilance scrutiny.

From the Chief Medical Officer
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SGHD/CMO(2018)12

For action
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Note - These are complex and long established reconstructive procedures and there are few if any viable alternatives. They are associated with a risk of harm and must be the subject of high vigilance scrutiny.

- ***Complex gynaecological mesh reconstructions, e.g. following cancer surgery***

  Not restricted; but subject to high vigilance scrutiny.

- ***Non-tape procedure for SUI (colposuspension, fascial slings and injectable treatments)***

  Not restricted; but subject to high vigilance scrutiny.

Note - It is appreciated that surgeons may not have recent experience of open or laparoscopic colposuspension in their practice. Colposuspension is a complex procedure with recognised complications and failures. While tape procedures are restricted it is likely that more colposuspensions will be performed and these will result in new harms. It is therefore important to mitigate this by including non-tape procedures for SUI in the high vigilance scrutiny e.g. colposuspension, fascial sling procedures, and periurethral injectable treatments.

- ***Non-mesh procedures for POP (colporrhaphy / vaginal hysterectomy / sacrospinous fixation*)**

  Not restricted: subject to high vigilance scrutiny at clinicians' discretion.

Note - many treatments in this category are long established and have recognised outcomes. Where there is no change in usual practice, then no additional scrutiny is required at present. However if there is uncertainty or if withdrawal of mesh results in a change in usual practice, then discussion with the relevant Health Board Accountable Officer (see below) is recommended and high vigilance scrutiny may be required.

- ***Mesh used in hernia repair***

  No change in practice – in line with NICE guidance.

- ***Mesh used in cervical sutures in Obstetrics***

  No change in practice – in line with NICE guidance.

- ***Male urological sling procedures***

  In line with NICE guidance - only to be performed as part of a well-conducted randomised clinical trial.

- ***Biological mesh procedures for SUI***

  Not to be substituted for synthetic mesh – insufficient evidence for routine use.

Measures required now to establish high vigilance scrutiny

In order to provide additional assurance for patients and taking into account the statement made by the Cabinet Secretary, I believe the following measures are now required. As a consequence of quality improvement work already undertaken many will already be in place. However greater assurance is needed. The adage "every patient, every time" must apply.

1. Identification of Accountable Officers

In each Health Board where procedures are performed, the Health Board Medical Director will identify an **Accountable Officer**. The Accountable Officer will be responsible for ensuring that the required high vigilance measures are followed in every case. The affirming clinician should be independent of the patient's clinical care, and need not be of that clinical specialty. **I ask that Medical Directors write to me with the name and contact details of their Accountable Officer by 12 October 2018**.

2. High vigilance scrutiny

This must include the following:

i. **Assurance of competence.** This may be of relevance for existing surgeons but will certainly be an important consideration for new Consultants and especially locum surgeons. This will be a crucial responsibility for both the Accountable Officer and Medical Director. Factors to be considered include:

-has s/he been appropriately trained
-has s/he actively maintained their skills
-has s/he a record of their practice
-is s/he recording every procedure on an agreed database.

ii. **Documentation of the decision making process**. The following are required:

- Details of shared decision making:
  - information provided,
  - choices considered and
  - consent of the patient.

This is a critical element of the high vigilance scrutiny and there must be assurance that the patient has been fully informed of the natural history of the condition, the risks and benefits of no treatment, conservative, non-surgical and surgical treatment options. The process must demonstrate that clinicians have secured and documented the agreement and consent of the patient.

- **Documentation from Multidisciplinary Team meetings (MDT)** This must include a record of attendance by clinicians at MDT meetings and the outcome of discussion regarding choices and the appropriateness of procedures for each patient.

iii. **Documentation and registration of all procedures on an agreed database.** Agreed with the relevant Accountable Officer.

iv. **Documentation of all mesh and non-mesh related complications on the database (above) and reporting of mesh related complications to Health Facilities Scotland Incident Reporting and Investigation Centre (IRIC)** **http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric/how-to-report-an-adverse-incident/**
This should be the responsibility of all clinicians involved in the care of patients.

v. **Documentation given to every patient treated with mesh detailing their procedure, the mesh or other product used (including product codes) and the name of the Surgeon.** Information should also be provided that will allow reporting by the patient of complications to MHRA via the Yellow Card scheme.

Work needed to consolidate expertise, to develop Specialist Centres and to establish a registry.

I appreciate this letter will be read as an instruction however, as we move forward it will be important that we work together in a collaborative manner to:

i. Review Restricted Use Protocol and high vigilance scrutiny implementation.
ii. Review NICE guidance - release of SUI and POP guideline for consultation in early October. This will support discussion and will indicate the future complexion of the service.
iii. Review case load to map activity and provision of service (including training).
iv. Consider referral pathways, delivery of care and resourcing of Specialist Centres.
v. Establish a common database / registry of procedures with recording of outcomes, including patient reported outcome measures. Colleagues from Scottish Government and Healthcare Improvement Scotland are currently working in partnership with representatives from the Department of Health In England and the devolved nations as well as from HQIP, RCOG, BAUS, BSUG and patient groups to establish a mesh registry that will collect information on all procedures.

My team will call a meeting in the near future and in the first instance this will involve Accountable Officers, representatives from Scottish Government and other relevant organisations. I anticipate this will be held either in the last week of October or the first week in November.

Finally, I am grateful to you for your co-operation and assistance. I appreciate the challenges these requests will impose on you but I hope we will be able to work together to find solutions and in so doing we will improve the care for women in Scotland.

Yours sincerely

Catherine Calderwood

DR CATHERINE CALDERWOOD