PE1517/BB

Cabinet Secretary for Health, Wellbeing and Sport
Shona Robison MSP

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The Scottish Government
Riaghaltas na h-Alba

LEGACY 2014
XX COMMONWEALTH GAMES
SCOTLAND

John Pentland MSP
Convener of the Public Petitions Committee
M1.21
The Scottish Parliament
Edinburgh
EH99 1SP
By e-mail
Petitions@scottish.parliament.uk

Your ref:
Our ref: A11028996
5 May 2015

Dear Mr Pentland,

Thank you for your correspondence dated 3 March and 24 April regarding polypropylene mesh medical devices, please accept my apologies for the delay in responding to your earlier letter.

The Scottish Government takes this issue very seriously and welcomes the Public Petitions Committee's interest. A copy of the evidence discussed by Mr Slater at the Committee meeting on 24 February was received on 21 April and on the same day passed to the Public health consultant carrying out the review of evidence for the Independent Review. I can also confirm that the Independent Review is reviewing the evidence provided by the Medicines and Healthcare Products Regulatory Agency (MHRA).

In February I met with Mrs Holmes and Mrs McIlroy and following this meeting I asked the Chief Medical Officer to write again to health boards reiterating our request that they consider suspending these procedures until the Independent Review has reported. This letter has now been issued to all health boards and primary care leads. I have enclosed a copy of all letters issued by the Office of the Chief Medical Officer.

I recognise however that some women, who are perhaps experiencing extremely difficult symptoms and having discussed options with their clinician, will decide that they still want to proceed. In these instances, the women concerned must first consider alternatives and be completely aware of the risks. I have asked that health boards follow a protocol to provide assurance that this process is being followed in every case. The protocol will be developed through the Scottish Government led Expert Working Group, set up to consider issues relating to mesh implants.

The number of procedures has reduced considerably following the former Cabinet Secretary's announcement. Published figures are not yet available for January but from 17 June until the end of December last year, health boards carried out 119 mesh implant procedures for stress urinary incontinence. The number of procedures for pelvic organ prolapse is too small to report, due to the risk of disclosure. I have enclosed a table providing numbers for each health board, however I am unable to provide information about whether these patients were on a waiting list prior to 20 June, this analysis, based on procedure, is not carried out due to data quality issues. As you are probably aware, prior to the request to suspend these procedures health boards carried out around 1,500 mesh implant procedures annually for stress urinary incontinence and 350 procedures for prolapse.

I think it is important to reiterate that regulation of medical devices, including implants, is a reserved matter and MHRA is responsible for regulating all medical devices in the UK and has the authority to remove a device form the market for the whole of the UK, where they have evidence to take such a step. The Scottish Government does not have direct powers to remove mesh products from use in NHS Scotland and current evidence suggests that the majority of women undergoing these procedures do not experience complications.

The Chair of the Independent Review has informed me that additional time is required to assess the evidence, a key element of this Review and to take account of the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks of the European Commission, which was due to be published in January 2015. My officials have written to the European Commission asking for confirmation of the publication date and assurance that their Report will be shared as soon as possible.

I therefore anticipate that the Independent Review will report in the summer and thereafter I will be happy to attend the Committee to give evidence.

SHONA ROBISON

Chief Medical Officer and Public Health Directorate

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The Scottish Government
Riaghaltas na h-Alba

In 2014 Scotland Welcomes the World

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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20 June 2014

SGHD/CMO(2014)15

Addresses
For action
Chief Executives, NHS Boards

For information
Medical Directors, NHS Boards
Directors of Public Health, NHS Boards
Chairs, NHS Boards

Further Enquiries

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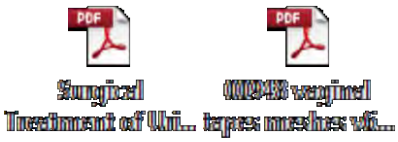
I understand women already on waiting lists for these procedures will be anxious as a result of this announcement and expect them to be offered the opportunity to discuss this with their consultant to allow them to review their decision in the light of evidence about the success and complication rates 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

Directorate of Chief Medical Officer

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The Scottish Government
Riaghaltas na h-Alba

Dear Colleague

TRANSVAGINAL MESH IMPLANTS

I am writing to provide an update on transvaginal mesh implants. The Independent Review Group has informed me that it will no longer report in March as more time is required to consider the evidence. I now expect the Independent Review to report its findings this summer.

I wrote to you in June 2014 to request that health boards consider suspending the use of these synthetic mesh products in surgery for pelvic organ prolapse and stress urinary incontinence. Our position has not changed and I ask again that you consider suspending these procedures until the Independent Review has concluded and reported.

The Independent Review has been 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 in early summer 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).

The investigation and management of all patients with these conditions should follow National Institute for Health and Clinical Excellence (NICE) guidelines which, whilst not mandatory in Scotland, are recommended as good practice. To provide assurance that the recommended management of these conditions is being followed, the patient pathway should be documented and available for audit.

The Scottish Government led Expert Working Group for transvaginal mesh implants, set up to look at issues relating to informed consent and pathways of care, will be developing a protocol and an additional support service for women who wish to speak to an informed clinician. I will notify you when the protocol has been developed and the support service is available.

From the Office of The Chief Medical Officer

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27 March 2015

SGHD/CMO(2015)5

Addresses

For action
Chief Executives, NHS Boards
Primary Care Leads

For information
Medical Directors, NHS Boards
Directors of Public Health, NHS Boards
Chairs, NHS Boards

As you are aware women may experience complications following insertion of these mesh implants, and adverse events should be reported to MHRA following the professional advice found at http://bsug.org.uk/MHRA.php

The Scottish Incident Reporting and Investigation Centre (IRIC) can also receive reports from patients and professionals which they will share with MHRA.
http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric/adverse-incident-reporting/

For information I am also attaching the link to the Patient Information and Consent Booklet on synthetic vaginal mesh mid-urethral tape procedure for the surgical treatment of stress urinary incontinence. This Booklet was developed by the Expert Working Group, which includes women affected by mesh complications, and should form the minimum content for your own information to women considering surgery.
http://www.gov.scot/Resource/0045/00453999.pdf

Yours sincerely

Catherine Calderwood

DR CATHERINE CALDERWOOD

Number of mesh tape procedures carried out (for stress urinary incontinence)
and number of mesh procedures carried out (for pelvic organ prolapse)
17th June 2014 - 30th September 2014
by health board of treatment

Health Board	Mesh Tape Procedures for Stress Urinary Incontinence	Mesh Procedures for Pelvic Organ Prolapse
Golden Jubilee National Hospital	-	-
NHS Ayrshire & Arran	*	*
NHS Borders	12	-
NHS Dumfries & Galloway	7	-
NHS Fife	*	-
NHS Forth Valley	5	-
NHS Grampian	12	-
NHS Greater Glasgow & Clyde	32	-
NHS Highland	-	-
NHS Lanarkshire	-	-
NHS Lothian	*	-
NHS Orkney	-	-
NHS Shetland	-	-
NHS Tayside	-	-
NHS Western Isles	*	-
Non-NHS Provider	-	-
Scotland	76	*

Source: SMR01, ISD Scotland
Ref: IR2015-00243 (FOI INFO-2015-000038)
Date: 18/02/15

Key to symbols

- zero

*Indicates values that have been suppressed due to the potential risk of disclosure and to help maintain patient confidentiality.

For more information see ISDs disclosure control policy:

http://www.isdscotland.org/About-ISD/Confidentiality/DISCLOSURE-PROTOCOL-VERSION-2-3_FULLVERSION.PDF

Notes

1. These statistics are derived from data collected on discharges from non-obstetric and non-psychiatric hospitals (SMR01) in Scotland. Only patients treated as inpatients or day cases are included. The specialty of geriatric long stay is excluded.

2. Data are based on date of discharge

3. Data relate to all women treated by the NHS in Scotland

4. Theses figures are episode based - an SMR01 episode is generated when a patient is discharged from hospital but also when a patient is transferred to a different hospital, significant facility, specialty or to the care of a different consultant.

5. Up to four procedures (one main procedure and three secondary procedures) may be recorded per hospital episode using the UK classification of Operative Procedures OPCS-4 (Office of Population Censuses and Surverys, Classification of Surgical Operation and Procedures). All four procedure positions were used to identify the relevant cases. The following codes have been used. Procedures for pelvic organ prolapse include vaginal procedures only.

Mesh Tape procedures for stress urinary incontinence	
Tension free trans-vaginal tape procedures	M53.3
Trans-obturator foramen tape procedures	M53.6
Mesh procedures for pelvic organ prolapse	
Colporrhaphy with mesh	P23.6, P23.7
Uterine suspension or vault repair with mesh	P24.6, Q54.6
(vaginal approach - infacoccygeal hysteropexy or colpopexy)	

Number of mesh tape procedures carried out (for stress urinary incontinence)
and number of mesh procedures carried out (for pelvic organ prolapse)
1st October 2014 - 31st December 2014
by health board of treatment

Health Board	Mesh Tape Procedures for Stress Urinary Incontinence	Mesh Procedures for Pelvic Organ Prolapse
Golden Jubilee National Hospital	-	-
NHS Ayrshire & Arran	-	-
NHS Borders	5	-
NHS Dumfries & Galloway	10	-
NHS Fife	9	*
NHS Forth Valley	-	-
NHS Grampian	*	*
NHS Greater Glasgow & Clyde	9	-
NHS Highland	-	-
NHS Lanarkshire	-	-
NHS Lothian	7	-
NHS Orkney	-	-
NHS Shetland	-	-
NHS Tayside	-	*
NHS Western Isles	*	-
Non-NHS Provider	-	-
Scotland	43	*

Source: SMR01, ISD Scotland
Ref: IR2015-00828
Date: 29/04/2015

Key to symbols

- zero

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For more information see ISDs disclosure control policy:

http://www.isdscotland.org/About-ISD/Confidentiality/DISCLOSURE-PROTOCOL-VERSION-2-3_FULLVERSION.PDF

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