# Northern Ireland Vaginal Mesh Review

# Progress Report 2017-2019



**Written by Christine McMaster on behalf of Working Group members, November 2019**

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## Executive summary

This report summarises the background to and describes the process, outputs and outcomes of the Northern Ireland (NI) Vaginal Mesh Review 2017- 2019 carried out at the request of the Department of Health (DoH) and supported initially by the Patient Client Council (PCC).

The need for this review arose from the widely publicised level and scale of complications women around the globe experienced following the vaginal insertion of synthetic mesh devices to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP).

It was undertaken by three multidisciplinary working groups that included women with vaginal mesh complications, Health and Social Care Trust (HSCT) clinicians and staff members of the Health and Social Care Board (HSCB) and the Public Health Agency between January and May 2018.

The members of the review's working groups were tasked with:

- Removing barriers patients and clinicians experience when managing suspected vaginal mesh related complications,
- Supporting patients in making informed choices in the treatment of SUI and POP,
- Improving access to multi-professional specialist teams for both patients and practitioners in each of the HSCTs and nationally, and
- Ensuring that future services for women requiring treatment for SUI and POP are of high quality.

In response, they designed patient pathways for vaginal mesh complications, made recommendations for improved data management

regarding clinical practice and patient outcomes and agreed mechanisms and resources to support informed consent.

Announcement of the vaginal mesh pause in July 2018 found NI HSCTs compliant with its requirements except for a UK wide Vaginal Mesh Register under development by NHS Digital with engagement from the devolved nations.

Members of the working groups engaged widely with the public, patient representatives and politicians throughout this review through a variety of media.

## 1. Introduction

In June 2017, media reports highlighted the difficulties of Northern Ireland women who had been seeking help for complications after surgery for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) using vaginally inserted synthetic mesh devices. This prompted many women to present to their General Practitioners (GPs) and gynaecologists reporting symptoms, which they associated with their previous surgery. At the same time, there were increased social media activity, heightened political interest and rising numbers of patient complaints on this subject.

At the request of the Department of Health in Northern Ireland, the NI Vaginal Mesh Review commenced in July 2017 (see Appendix A for timeline). This review, led by a public health consultant from the NI Public Health Agency (PHA), engaged with patients, clinicians, politicians, members of the public and civil servants in three work streams to develop a network for multidisciplinary team (MDT) working, patient pathways, data management processes, informed consent materials, public information and professional advice.

At the outset the Health and Social Care Board (HSCB) wrote to the Health and Social Care Trusts (HSCTs) and GPs in NI advising them of the importance of listening to women's concerns and promptly referring and assessing those with potential vaginal mesh related complications (Appendix B).

A workshop was convened with clinicians on 11 September 2017 (Appendix C) to identify issues and agree the approach to the review. A meeting took place with women affected by complications associated

with vaginally inserted mesh on 27 October 2017 (Appendix D). These meetings identified the following issues to be addressed:

a) **Removing barriers patients and clinicians experience when managing suspected vaginal mesh related complications,**

b) **Supporting patients in making informed choices in the treatment of SUI and POP,**

c) **Improving access to multi-professional specialist teams for both patients and practitioners in each of the HSCTs and nationally, and;**

d) **Ensuring that future services for women requiring treatment for SUI and POP are of high quality.**

Addressing and resolving these issues required the design and agreement of **patient pathways** for women who have had surgery for SUI and POP using vaginally inserted mesh and for those who suffer from SUI and POP now and in future, to ensure that all women in NI have access to consistently high quality urogynaecological services.

It was further necessary to ensure that **data about clinical practice and patient outcomes** are systematically recorded and used to quality assure services for women with SUI and POP both before and after treatment.

Mechanisms needed to be identified that support clinicians and patients in communicating effectively when discussing and deciding on treatment options, regardless of whether these involve surgery using vaginally inserted mesh, to fulfil the requirements of **informed consent**.

## 2. Background

Surgery using vaginally inserted synthetic mesh devices has been practiced as one of a range of treatments for stress urinary incontinence (SUI) for several decades. Following the introduction of such mesh devices for SUI, other mesh operations were developed for women with pelvic organ prolapse (POP). Based on experience with mesh repairs of hernias since the middle of the 20th Century, it was known that the use of synthetic mesh devices can be used successfully to reinforce natural tissues. It was therefore assumed that surgery using vaginally inserted synthetic mesh would be more effective in curing SUI and POP in the long term than other surgery.

### Pelvic Organ Prolapse

In light of increasing evidence in the published research literature of high complication rates following surgery for POP using vaginally inserted mesh, the use of vaginal mesh devices for POP declined and had ceased in NI by April 2016 due to changes in the practice of individual surgeons here. NICE subsequently confirmed this clinically driven development by publishing Interventional Procedural Guideline (IPG) 599 in 2017.

### Stress Urinary Incontinence

In the treatment of SUI, only retropubic midurethral tension free transvaginal tapes (TVT) remained in common practice in NI by 2017, whilst transobturator tapes (TVTO) were rarely used because published research had shown a higher risk of long term post-operative pain than those using TVT.

Mesh is classified as a medical device in the United Kingdom and is therefore subject to regulation by the Medicines and Healthcare products Regulation Agency (MRHA). The MHRA continue to encourage reporting of adverse incidents involving medical devices to its Yellow Card scheme for monitoring and reviewing their safety and efficacy. Medical device incidents in NI should be reported the Northern Ireland Adverse Incident Centre (NIAIC), which collates and investigates these and liaises with the MHRA. They can also be reported directly to the Health and Social Care (HSC) Business Services Organisation (BSO) if procured by them on behalf of end users like HSCT clinicians.

## 3. Methodology

Following the workshop in September 2017 and stakeholder engagement, three working groups were established to address the areas of concern. Multidisciplinary membership was sought from HSCTs, primary care providers and patient representatives via the Patient Client Council's (PCC) membership scheme, with preference being given to women who were engaging with NI HSC services at the time of recruitment.

In light of ongoing public concern surrounding this issue the review team identified the need to share information regarding its work as it progressed. With support from HSC communications and public relations staff, a live frequently asked questions (FAQs) document was developed in December 2017 and published on the HSCB website.

The FAQs have been updated on several occasions to take account of changing circumstances and can be found at

http://www.hscboard.hscni.net/our-work/commissioning/mesh-frequently-asked-questions/

The working groups met between January and March 2018 to develop solutions to overcome existing challenges and make recommendations for future service delivery improvements. A further meeting with patient representatives in May 2018 collated final comments on selected patient information resources.

Pending the completion of this report, the HSCB advised HSCT Chief Executive Officers (CEOs) of the review's recommendations in June 2018.

A vaginal mesh pause was announced in July 2018 by the Department of Health. Northern Ireland's HSCTs at that stage were well advanced in working towards compliance with its requirements, some of which extended beyond gynaecological surgery, and fully compliant when its duration was extended in April 2019 according to HSCB monitoring reports.

The only outstanding element for NI surgeons at that time appeared to be participation in a UK wide mesh register, the development of which is being taken forward with involvement of the devolved administrations led by NHS Digital, but it has since become apparent that full recurrent funding for the BHSCT vaginal mesh centre also remains outstanding.

In December 2018, two of the working groups including patient representatives reconvened to prepare for HSCT and NI wide multidisciplinary team working in line with revised NICE guidance since published in April 2019 and revised in June 2019. The intention was to develop on line patient referral forms to reflect patient pathways and a minimum data set for monitoring and evaluation with the support of the NI Electronic Care Record (NIECR) team but had to cease in light of the ENCOMPASS programme taking precedent.

The review team has continued to engage with patients, advocacy group leaders and politicians and met with them in a variety of contexts to renew trust and promote appropriate levels of confidence in redesigned NI complex urogynaecological services that deliver patient care of high quality.

## 4. Working Group Findings and Recommendations

### *4.1 Multidisciplinary Teams and Patient Pathways*

This working group met twice. The Terms of Reference and membership of this group are in Appendix E.

### *4.2 Multidisciplinary Teams*

The initial meeting in January 2018 assessed the configuration of each HSCT urogynaecological service, its surgical capabilities and practice and resulting referral thresholds for women seeking surgical treatment for SUI and management of mesh complications. This was necessary to understand existing practice and service capability to inform future service provision.

The findings are summarised in Appendix F and represent the situation in early 2018.

### *4.3 Patient Pathways*

The working group agreed outline patient pathways for women presenting with vaginal mesh complications. They were revisited and finalised after publication of revised NICE guidance in mid 2019.

Feedback from patients indicated a preference for non-invasive investigations; however the broad range of potentially necessary invasive and non-invasive investigations were considered, because non-invasive investigations are not normally sufficient to fully assess and diagnose women who experience complications after surgery. It was agreed that every patient requires an individually tailored combination of investigations, some of which may be invasive.

With revised NICE guidance for the management of SUI expected in 2019, the following interim recommendations for service improvements were agreed:

1.1 Explore how pelvic floor exercises and community continence services can be used more widely to prevent and conservatively manage SUI to reduce the need for surgery;

1.2 Resource HSCT MDTs to implement NICE clinical guideline 79; this requires job planning and clerical support;

1.3 Monitor numbers of surgeries performed and reduce number of operators in accordance with existing NICE CG 79 as necessary;

1.4 Support training in surgical procedures that provide alternatives to vaginal mesh in the management of SUI;

1.5 Resource development of the BHSCT Northern Ireland Mesh Centre, including a monthly NI wide multidisciplinary virtual meeting (MDM);

1.6 Consider the impact of managing women with mesh related complications on other clinical services, patients and staff;; and;

1.7 Share MDT, discharge and follow up clinical letters with patients.

## 5. Data collection, audit and quality assurance

This working group met in January 2018. Its Terms of Reference are in Appendix G.

Its tasks were to:

- Review coding processes for surgical treatment of SUI, POP and mesh complications,
- Make recommendations for improved coding practice and how to capture patient follow up outpatient data,
- Explore the potential of NIECR to support data collection for monitoring of patient outcomes, audit and other service quality improvement activities,
- Identify what is needed to make the comprehensive use of national registries and databases feasible for Northern Ireland clinicians.

### *5.1 Clinical Coding*

The group produced guidance for Northern Ireland HSC clinicians and coders to help improve the accuracy in the recording and coding of the clinical conditions being treated, including surgical procedures and management of complications.

This technical document is included in Appendix H.

### *5.2 Northern Ireland Electronic Care Record (NIECR) and Registries*

It agreed with NIECR colleagues to explore the feasibility of establishing a patient pathway on the NIECR for the management of women with SUI to provide data on patient care processes and outcomes. This work commenced in December 2018.

The Group noted the absence of a national registry for mesh devices and uncertainty surrounding the use of the MHRA yellow card scheme for notifying vaginal mesh complications.

It was apparent that the time needed to complete existing BAUS and BSUG clinical outcomes databases was difficult to sustain within existing resources.

The recommendations arising from this group are:

2.1 Disseminate and implement guidance for clinicians and coders through existing processes;
2.2 Establish a task and finish group with NIECR colleagues to explore the feasibility of using existing MDT functions for data collection and develop a business case if appropriate; and;
2.3 Participate in UK initiatives to improve the regulation of medical devices including vaginal mesh products, data collection and analysis.

## 6. Patient information and consent

This working group met twice in January and March 2018, followed by a task and finish group meeting with patient representatives in May 2018 to action one of its recommendations. It's Terms of Reference and membership is in Appendix I.

Its tasks were to:

- Review information leaflets, consent forms and check lists currently in use by clinicians who treat women with SUI;
- Arrive at an agreed and sufficiently comprehensive but as concise as possible suite of resources for women considering surgery for SUI in Northern Ireland; and;
- Outline good practice for arriving at informed consent with women considering surgical treatment of SUI.

### *6.1 Patient Information*

Most of the existing resources had been developed, endorsed and published by different professional organisations and parts of the NHS, usually in collaboration with service users.

Some group members favoured the development of new Northern Ireland resources, but agreed to recommend, with some reservations especially from patient representatives, the use of the BAUS and NHS leaflets.

These reservations were identified and captured at a meeting of patient representatives with PHA representatives in May 2018 (Appendix J) and have since been shared with BAUS and the NHS so they can be taken account of in future revisions of these resources.

### *6.2 Informed Consent*

Policy on consent in Northern Ireland is set out in the Reference Guide to Consent for Examination, Treatment or Care, which at the time of writing could be found here:

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/consent-ref-guide.pdf

Doctors' practice is further informed by a range of professional organisations, notably the professional regulator, the General Medical Council, which has 2008 guidance on informed consent.

The discussions surrounding good practice in arriving at informed consent did not arrive at recommending a single approach but acknowledged that every patient's decision making process is an individual one. Clinicians need to be flexible in their approach to meet each patient's information needs.

Communication skills vary and patients' ability to play an active role in seeking shared understanding before deciding on a particular form of treatment depends on many factors, including health literacy, which clinicians need to take into account.

Patients and their families share the responsibility of arriving at informed consent and should be encouraged to inform clinicians if they find it difficult to understand their treatment options and arrive at a decision. The working group's recommendations were:

3.1 All HSCTs should consistently use the agreed BAUS and NHS suite of leaflets and consent processes together with the Northern Ireland DoH consent form;

3.2 Patients need to receive the agreed suite of leaflets in a form that is in keeping with their preferences. They should read, seek clarification if necessary and keep documentation for future reference;

3.3 The PHA will continue to explore the mechanism by which NHS leaflets can be customised for use in Northern Ireland, and;

3.4 Clinicians should consider using IUGA leaflets, available in a variety of languages, in addition to the agreed suite of leaflets along with interpretation services for non-English speaking patients.

## Recommendations Summary and Action Plan

| Number | Recommendation March 2018 | Update November 2019 | Responsible |
|---|---|---|---|
| 1.1 | Explore how pelvic floor exercises and community continence services can be used more widely to prevent and conservatively manage SUI to reduce the need for surgery | HSCB and PHA are undertaking a review of community continence services to address this issue amongst others | HSCB and PHA |
| 1.2 | Resource HSCT MDTs to implement existing NICE clinical guideline 79; this requires job planning and clerical support | HSCTs received non recurrent transformation funding in 2018/19 for this | HSCB |

| Number | Recommendation March 2018 | Update November 2019 | Responsible |
|---|---|---|---|
| 1.3 | Monitor numbers of surgeries performed and reduce number of operators in accordance with existing NICE CG 79 as necessary | HSCTs undertook this function until the vaginal mesh pause began in July 2018; a NI complex urogynaecological services needs assessment began in March 2019 | HSCTs supported by PHA and HSCB |
| 1.4 | Support training in surgical procedures that provide alternatives to vaginal mesh in the management of SUI | HSCTs received non recurrent transformation funding in 2018/19 for this, but the NI needs assessment begun in March 2019 will review training needs | HSCTs supported by PHA and HSCB |

| Number | Recommendation March 2018 | Update November 2019 | Responsible |
|---|---|---|---|
| 1.5 | Resource development of the BHSCT Northern Ireland Mesh Centre including an NI wide multidisciplinary virtual meeting (MDM) | BHSCT only received part of the funding required to fully develop the mesh centre on a non recurrent basis | HSCB |
| 1.6 | Consider the impact of managing women with mesh related complications on other clinical services, patients and staff | Especially in BHSCT women with mesh complications continue to displace other BHSCT urogynaecological patients from outpatient clinic and theatre slots. Increasing the mesh centre's capacity is needed to remedy this | HSCB and BHSCT |

| Number | Recommendation March 2018 | Update November 2019 | Responsible |
|---|---|---|---|
| 1.7 | Share MDT, discharge and follow up clinical letters with patients | BHSCT MDT letters are being shared with patients; this practice is expected to spread through NI wide MDM working beginning in May 2020 | PHA and HSCTs |
| 2.1 | Disseminate and implement guidance for clinicians and coders through existing processes | In final draft | HSCB |
| 2.2 | Establish a task and finish group with NIECR colleagues to explore the feasibility of using existing MDT functions for data collection and develop a business case if appropriate | In progress | PHA |

| Number | Recommendation March 2018 | Update November 2019 | Responsible |
|---|---|---|---|
| 2.3 | Participate in UK initiatives to improve the regulation of medical devices including vaginal mesh products, data collection and analysis | Ongoing | DoH |
| 3.1 | All HSCTs should consistently use the agreed BAUS and NHS suite of leaflets and consent processes in addition to the Northern Ireland DoH consent form | Implemented | |

| Number | Recommendation March 2018 | Update November 2019 | Responsible |
|---|---|---|---|
| 3.2 | Patients need to receive the agreed suite of leaflets in a form that is in keeping with their preferences. They should read, seek clarification if necessary and keep documentation for future reference | Implemented | |
| 3.3 | The PHA will continue to explore the mechanism by which NHS leaflet can be customised for Northern Ireland | Patient representatives' comments sent to BAUS; NHS leaflet customisation in progress | PHA |

| Number | Recommendation March 2018 | Update November 2019 | Responsible |
|---|---|---|---|
| 3.4 | Clinicians should consider using IUGA leaflets, available in a variety of languages, in addition to the agreed suite of leaflets along with interpretation services for non-English speaking patients | Implemented | |

## Appendices

**Appendix A**

**Timeline 2017/18**

| | Jun 17 | Jul 17 | Aug 17 | Sept 17 | Oct 17 | Nov 17 | Dec 17 | Jan 18 | Feb 18 | Mar 18 | Apr 18 | May 18 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Letter to GPs and HSCTs | | | | | | | | | | | | |
| Meeting with PCC and clinicians | | | | | | | | | | | | |
| Meeting with PCC and patients | | | | | | | | | | | | |
| Briefing for patients on PHA and HSCB websites | | | | | | | | | | | | |
| Project planning | | | | | | | | | | | | |
| PCC newsletter invite for patient participation | | | | | | | | | | | | |
| BHSCT registers as RCOG MESH centre | | | | | | | | | | | | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FAQ on PHA, HSCB and HSCT websites | | | | | | | | | | | | |
| Briefing to media | | | | | | | | | | | | |
| Shortlisting of patient applications | | | | | | | | | | | | |
| Responses to patient applicants | | | | | | | | | | | | |
| Patient introductory meeting | | | | | | | | | | | | |
| First working group meetings | | | | | | | | | | | | |
| Second working group meetings | | | | | | | | | | | | |
| Third working group meetings | | | | | | | | | | | | |
| Final report | | | | | | | | | | | | |

## Appendix B

## Letters to HSCTs and GPs in July 2017

Health and Social Care Board

*Health & Social Care Board*
*12-22 Linenhall Street*
*BELFAST BT2 8BS*

*Tel : 0300 555 0115*
*Web Site : www.hscboard.hscni.net*

Trust Chief Executives

31 July 2017

Dear Colleagues

**Management of women experiencing complications following vaginal mesh surgery.**

You may be aware of the recent media publicity regarding the problems women encounter following vaginal mesh surgery. Two reports have been issued on the subject this year from Scotland (March 2017) http://www.gov.scot/About/Review/Transvaginal-Mesh-Implants and England (July 2017) https://www.england.nhs.uk/publication/mesh-oversight-group-report/.

Mesh surgery is used to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP). For many women suffering the distressing symptoms of SUI and POP, surgical procedures using mesh devices have provided an effective form of treatment which are less invasive than alternative surgical procedures. There is published evidence to suggest improved outcomes for procedures using mesh over the periods studied, but complications are also recognised. However the period of follow up in these studies is limited. Although published research suggests the risk of complications from surgery using mesh falls within acceptable limits, an increasing number of women have reported complications, sometimes many years after their surgery. For some patients the complications can be severe and life-altering.

I have attached a copy of a letter which is being sent to all GPs in N Ireland. They have been advised that if they encounter any woman experiencing problems after vaginal mesh surgery they should be referred back to the Trust where the surgery was performed and the referral letter should state that the woman is being referred because of problems associated with mesh surgery. Trusts should have arrangements in place for these women to seen promptly by a consultant with an interest in urogynaecology.

I would ask you to ensure that your Trust has clear arrangements in place for patients referred by GPs with problems post vaginal mesh surgery to ensure they are seen by a consultant with an interest in urogynaecology. A clinical workshop will be held on the 11th September 2017 to finalise a regional consent form, regional information leaflet and ensure consistent use of the national database for vaginal mesh surgery to record information on all women who have these procedures.

Your co-operation with these arrangements is greatly appreciated.

Yours sincerely

Valerie Watts

Valerie Watts
Chief Executive

Encs

Health and Social Care Board

Directorate of Integrated Care
Health and Social Care Board
12-22 Linenhall Street
Belfast
BT2 8BS

Tel : 028 95363926
Fax : 028 95363126
Web Site: www.hscboard.hscni.net

TO:- All GP's in Northern Ireland
GP OOH Providers

31st July 2017

Dear Colleagues

**Re: Management of women experiencing complications following vaginal mesh surgery.**

You may be aware of the recent media publicity regarding the problems women encounter following vaginal mesh surgery. Two reports have been issued on the subject this year, one from Scotland (March 2017): http://www.gov.scot/About/Review/Transvaginal-Mesh-Implants and one from England (July 2017) https://www.england.nhs.uk/publication/mesh-oversight-group-report/.

Mesh surgery is used to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP). For many women suffering the distressing symptoms of SUI and POP, surgical procedures using mesh devices have provided an effective form of treatment which are less invasive than alternative surgical procedures. There is published evidence to suggest improved outcomes for procedures using mesh, over the periods studied, but complications are also recognised. However the period of follow up in these studies is limited. Although published research suggested the risk of complications from surgery using mesh falls within acceptable limits, an increasing number of women have reported complications, sometimes many years after their surgery. For some patients the complications can be severe and life-altering.

This letter is to clarify arrangements in Northern Ireland. If any of your patients present experiencing problems after vaginal mesh surgery they should be referred back to the Trust where the surgery was performed and the referral letter should state that the patient is being referred because of problems associated with mesh surgery. Individual Trusts should have arrangements in place for these women to be seen by a consultant with an interest in urogynaecology.

Your co-operation with these arrangements is greatly appreciated.

Yours sincerely

Margaret O'Brien

Dr Margaret O'Brien
Head of GMS

cc. Dr Brid Farrell, Assistant Director of Service Development, Safety & Quality, PHA

**Appendix C**

**MESH Workshop Report**

**Bretten Hall, Antrim Area Hospital**

**Monday 11 September 2017**

**10.00-13.00**

***Aim:***

To improve services for women requiring surgery for urinary incontinence and pelvic organ prolapse involving (amongst others) MESH procedures

***Objectives:***

To agree scope and scale of the work required

To establish baselines and reporting arrangements

To develop regionally agreed patient information, consent, audit and multidisciplinary team working

To find meaningful ways of patient engagement

To contribute to a final report and recommendations for future work

**Workshop 1- patient information and consent**

***Action:***

Develop **regional patient information leaflet of and consent form for all available primary stress urinary incontinence procedures**, drawing on existing good ones and including information on what procedures are available in which HSCT/site (lead Penny Hill)

***Considerations:***

Introduce consent clinics/ designated appointments?

Address variation in use of conservative measures by primary care providers!

**Workshop 2- audit and information management**

***Action:***

Agree **minimum dataset** including patient related outcomes (PROMS) (lead TBA)

***Considerations:***

Develop group codes including for mesh removal?

Explore options for data collection, recording and analysis- BAUS vs BSUG vs ECR vs made in NI?

Make recommendations for good audit practice to maintain license to practise?

Minimise use of independent sector because of poor coding practice!

**Workshop 3- patient pathways and multidisciplinary team meetings**

***Action:***

Establish **regional MESH centre and MDT** including psychology and pain management input- consider link with MESH centre in GB (lead Lucia Dolan) and ECR criteria

Specify **recommended scope of local MDTs, patient pathways and referral** (lead TBA)

**All-patient engagement and participation**

***Action:***

Meet with **MESHED UP NI** and explore options also to include **representatives of majority of satisfied patients** (lead Richard Dixon)

***Considerations:***

Share letters with patients

**Appendix D**

## Meeting Report

**Date of Meeting:** Friday 27 October 2017

**Attendees:** Christine McMaster, Public Health Agency

Mr Richard Dixon, Patient and Client Council

Eleanor O'Hare, Patient and Client Council

Members of Meshed Up NI (15)

Independent Patients (2)

### Purpose of the Meeting

The meeting was organised to allow the PHA to update members of the patient group Meshed Up NI and some other patients with concerns about Mesh Surgery on the actions taken and planned by Health and Social Care to address patient concerns over vaginal mesh implant surgery.

### Overview and Update by Dr McMaster, Public Health Agency

Background to the Issue

Mesh had been in use for several decades for the repair of abdominal tears and similar non-complex wounds and ruptures.

It was assumed that Mesh would be suitable for use in management of prolapse and urinary incontinence in women given its history in other forms of abdominal repair.

As a result, testing of the suitability of Mesh for such procedures was not as rigorous as would have been the case for an entirely new product.

That there was a problem with the use of Mesh for these purposes emerged only gradually due to complications arising over time and being difficult to discern within an individual clinician caseload or a single service.

It became clear after some time that there was a failure rate between 5% and 10% in certain procedures – which rate of failure is above that regarded as acceptable for procedures of this type.

Problems had been identified definitively by 2012. At that time the Department of Health, Social Services and Public Safety wrote to all Health and Social Care Trusts directing them to review their practice in this area and confirm that NICE guidelines were being implemented.

It became clear in 2017 with the publication of the Scottish and English reports that action taken to date had not been sufficient to address the problem.

Actions taken since July 2017

The Health and Social Care Board (HSCB) wrote to all GPs in Northern Ireland advising them to refer any patient presenting with difficulties following vaginal mesh surgery to the HSCT Trust that had provided the original service, i.e. where the surgery had been performed.

At the same time, the HSCB wrote to all HSCTs directing them to make provision for the assessment and treatment of women presenting with symptoms associated with problems after vaginal mesh surgery.

Staff from the Public Health Agency (PHA) were appointed to lead a service review and response to the issue and organised a clinical workshop in early September 2017, at which were present clinical representatives of each of the Health and Social Care Trusts responsible for the provision of vaginal mesh surgery.

Priorities agreed at the Clinical Workshop

This workshop identified the following priorities for action:

- To review the operation of multi-disciplinary teams in each Trust and the range of procedures available within each with the aim of establishing effective regional practice including the creation of a regional Mesh Centre and associated regional specialist multi-disciplinary team
- To review clinical coding practice in relation to vaginal mesh implant surgery in recognition that shortcomings in clinical coding had made it difficult to establish the number and types of surgeries performed
- To ensure in as far as possible within the constraints of existing information management systems that service activity and patient outcome data are audited for quality assurance purposes
- To develop appropriate regional patient information on all aspects of vaginal mesh surgery and its alternatives and to reduce the number and range of leaflets covering different procedures in different HSCTs
- In addition to reviewing thoroughly the information given to patients it was agreed that it was important to review also the process of consent. It was clear from the concerns raised by patients that many felt strongly that they had not been informed of the risks of the surgery.

In the development of a regional mesh centre and multi-disciplinary team there are plans for the provision of additional training and for the effective management of extra contractual referrals for any patient requiring treatment outside Northern Ireland.

Assurances were given that all recommendations for referral for treatment outside Northern Ireland are processed without undue delay.

It was likely that as a result of these service developments and changes that fewer doctors would be carrying out vaginal mesh surgery in future.

Action Plan

The PHA will produce a report with specific actions and initiate change over the next few months. The Public Health Agency is in the process of identifying clinical leads to see through the changes needed.

**Input from Service Users**

Experience of living with Mesh complications and engaging with services

All of those service users, who spoke, described their experience of living with complications following mesh surgery. These included:

- The severe impact of living with chronic and disabling pain
- The serious impact on intimate relationships in some cases leading to the end of marriages and in others undermining confidence in pursuing any new relationship
- The impact on family and working life of chronic pain; of mobility difficulties; of repeated and debilitating infections and the consequences of multiple appointments and waits for treatment and care that in many instances proved ineffective or irrelevant to the cause of the problems
- This included the loss of livelihood and the inability to work for some present
- It was a common experience among those service users present that when they raised their concerns with clinicians they were met with denial, in some cases to the point of angry denial, that their symptoms were related to their vaginal mesh implant

- Many felt strongly that this “anything but the mesh” attitude from clinicians put them into a cycle of ultimately futile waits for diagnostic tests and referrals to services such as pain management

Given this range of symptoms, the difficulties they caused and the defensiveness of service providers, those present stated that the action taken by Health and Social Care (HSC) services would need to be rapid, meaningful and effective in responding to people currently affected and protecting other women from the consequences of surgery with which they were all living.

Specific Concerns

Specific concerns about aspects of services raised by service users present included:

*Suspension of mesh procedures* – the campaign group Meshed Up NI calls for an immediate suspension of the use of mesh until services have been reviewed and changed as needed. There was widespread concern for the welfare of women who may currently be undergoing these procedures.

*Diagnostic Testing* – diagnostic tests – and the fact that women were referred frequently for them – were experienced as invasive and risking further harm as a result. Fear of further nerve damage, for example, was raised. Less invasive options for diagnostic testing – such as trans labial ultrasound scanning – should be part of routine service provision and investigation without the risk of further harm.

*Waiting Times* – as a result of multiple referrals both for testing and for treatment many of those present had experienced one lengthy wait after another in their attempts to find resolution of their difficulties. Something

needed to be done to expedite referrals and ensure timely access to appropriate treatment and care.

*Extra Contractual Referrals* – for those patients seeking services outside Northern Ireland there were lengthy waits – counted in months and years – to establish that an ECR was appropriate and then to proceed to treatment and care. Action was needed to ensure that in ECRs – as in the rest of service provision – that women did not experience long waits while living with significant pain and disability.

*Removal on request* – That a woman should have the right to have the mesh removed if she asked for this to be done was raised as an issue for service users.

*Trust* – while those present respected that no-one present could answer for the actions of doctors in relation to individual patients, it had been common experience of many service users present that clinicians were resistant to acknowledging that symptoms may have arisen from the mesh implant. This went beyond the actions taken by clinicians to eliminate other possible causes as part of a process of clinical assessment. It was for many present a desire to avoid ascribing the symptoms to mesh. This experience damaged trust and confidence in clinicians and this would need to be acknowledged and addressed in the actions taken by the service to change services.

**Initial Responses by Dr McMaster to the issues raised**

*Consent* – this will form part of the review of services and the action plan

*Patient Information* – as with consent, this will form part of the review and action plan

*Assurances on clinical quality and training* – the establishment of a regional mesh centre will include provision for further specialist training

and patient referral to a regional expert hub for assessment, treatment and care where this cannot be provided locally.

*Timely provision of services* – for those women presenting with concerns about Mesh, all Trusts were trying at present to expedite all such referrals and to offer double appointments as needed to ensure adequate and thorough review and discussion of assessment and treatment plans with patients.

*Extra Contractual Referrals* - With regard to the Extra Contractual Referral process, while it was noted that the actual approval process within the HSCB operated swiftly as the decision panel met weekly it was acknowledged that it took time for local clinicians to gather evidence to support, draft and submit requests. Also, it was noted that where an Extra Contractual Referral was approved the effect was to place the patient on the waiting list for the doctor outside Northern Ireland. The general problems of waiting times for some health and social care services are widely reported and understood.

*Suspension* – concern for the welfare of people undergoing mesh procedures at present was noted and fully acknowledged. Dr McMaster noted that a number of procedures had been discontinued several years ago as they presented particular problems. Dr McMaster noted also that the comprehensive action plan that was under way to review Mesh services would help safeguard the treatment and care of current and future patients. Finally, while acknowledging absolutely the difficulties that a poor outcome in mesh surgery presented, it needed to be noted that for more than 95% of people the operation was successful and brought lasting benefits.

*The Right to Removal* – Whether or not removal was the best or most appropriate option for an individual patient needed to be a matter of discussion between individual patients and their doctors. However, Dr McMaster did inform those present of their right to a second opinion from another doctor. Dr McMaster also confirmed that there were doctors in Northern Ireland suitably trained and skilled to remove mesh implants where this was the best course of action for the patient.

*Alternatives to Mesh Implant Surgery* – Dr McMaster had noted comments made throughout the meeting about surgical alternatives to mesh surgery. Dr McMaster stated that ensuring women had access to the full range of options to address their treatment and care needs was fundamental to the aims of the plan to review all mesh services.

**Next Steps**

The PCC would produce a note of the meeting and circulate this to all who attended.

The PHA would consider further all that had been said and come back to service users to update them on the development and implementation of the action plan, including service user involvement in the overall development of services.

**Appendix E**

## MESH MDT Working Group

### Aim

To improve services for women requiring surgery for urinary incontinence and pelvic organ prolapse involving (amongst others) MESH procedures

### Objectives

To agree scope and scale of the work required

To establish baselines and reporting arrangements

To develop regionally agreed multidisciplinary team working and patient pathways

To find meaningful ways of patient engagement

To contribute to a final report and recommendations for future work

### Modus operandi

To meet approximately monthly until present objectives are achieved

To advise at that point how the working group might change

To produce a brief record of meetings

To agree and share agenda and papers a week before meetings

To undertake work between meetings to achieve objectives

To collaborate with working group members and others relevant in the context of this project

To maintain confidentiality and communicate respectfully and appropriately within and out with meetings

## Appendix F

## Findings

### *BHSCT*

Three surgeons were offering TVT, burch colposuspension, bulking and autologous fascial sling. They were capable of removing TVT and TVT-O as completely as possible and required, including mesh eroded into bowel, bladder and urethra, but, like other UK mesh centres, lacked experience in removing vaginal mesh used to treat POP.

The MDT met monthly, which was included in job plans. Pain management but no psychology staff attended. Only patients awaiting complex primary SUI surgery, reoperations and other complex urogynaecological procedures including mesh complications were discussed.

The service was registered by the Royal College of Gynaecologists (RCOG) as a mesh centre in December 2017 but required investment to be fully operational in line with patient need and contribute to an evolving tertiary pelvic floor service in BHSCT.

### *NHSCT*

Three surgeons worked across Causeway Hospital in Coleraine and Antrim Area Hospital offering TVT, bulking, burch colposuspension and autologous fascial sling; any women requesting the latter was referred to BHSCT.

All patients with suspected mesh complications attended one surgeon capable of partially removing TVT and TVT O vaginally but had neither urology nor colorectal surgery colleagues locally, so referred patients with other more complex mesh complications to either WHSCT or BHSCT.

The MDT met monthly, was in consultant job plans and discussed all patients for primary SUI surgery.

***SEHSCT***

Three surgeons offered urogynaecological procedures, including TVT, colposuspension, bulking agents and autologous fascial slings to women considering surgery for SUI. They were retraining in colposuspension, planned training in use of bulking agents and meantime referred patients for this as well as autologous fascial sling surgery to Belfast.

They intended to divide future work load depending on procedure numbers, so each surgical procedure would have at least two surgeons trained in it while also ensuring that each operator performed sufficient numbers of any given procedure from a governance perspective.

The MDT met bimonthly, was not in current job plans nor had pain management, psychology or secretarial support staff attending, but all patients for primary SUI surgery were discussed, as were all patients with mesh complications.

If patient requirements for primary SUI or complex mesh removal surgery could not be met locally, women were referred to Belfast.

***SHSCT***

A small number of designated surgeons in Craigavon Area and Newry Daisy Hill Hospitals offered TVT, burch colposuspension, bulking agents and autologous fascial sling surgery to women seeking surgical treatment for SUI. This number was kept under regular review to maintain the required number of procedures per operator and meet NICE guidance in existence at the time.

Some of these surgeons were capable of removing TVT and TVT-O as completely as possible and required, including mesh eroded into urethra and bladder; bowel eroded mesh could be treated with the help of local laparoscopically experienced bowel surgeons.

The MDT met monthly out of hours without being included in job plans and had no pain management nor psychology staff members. In line with then existing NICE guidance, it discussed all patients for SUI and mesh complication surgery.

***WHSCT***

Seven surgeons in South West Area Hospital in Enniskillen and Altnagelvin Area Hospital in L/Derry offered TVT, bulking, autologous fascial sling and burch colposuspension, but needed to retrain to perform the latter locally so were referring to BHSCT if patients chose this procedure.

There was capability to remove TVT laparoscopically and deal with urethra, bladder and bowel mesh exposure, but latter had not yet been needed. There was no need for POP removal expected, because only one such procedure was ever undertaken within the NHS in WHSCT.

The MDT met monthly, ran on both hospital sites connected via videolink and was not in every participant's job plan; therefore and contrary to NICE guidance not all surgeons attended, physiotherapists found it difficult to attend due to other work load, and nurses were mostly able to attend, but there was no pain management, psychology or administrative support staff available to participate; all patients awaiting SUI or mesh complication surgery were being discussed.

**Appendix G**

## MESH DATA Working Group

### Aim

To improve services for women requiring surgery for urinary incontinence and pelvic organ prolapse involving (amongst others) MESH procedures

### Objectives

To agree scope and scale of the work required

To establish baselines and reporting arrangements

To develop regionally agreed arrangements for data management, audit and quality assurance

To find meaningful ways of patient engagement

To contribute to a final report and recommendations for future work

### Modus operandi

To meet approximately monthly until present objectives are achieved

To advise at that point how the working group might change

To produce a brief record of meetings

To agree and share agenda and papers a week before meetings

To undertake work between meetings to achieve objectives

To collaborate with working group members and others relevant in the context of this project

To maintain confidentiality and communicate respectfully and appropriately within and outwith meetings

**Appendix H**

**Mesh Data Working Group - Guidance for Clinical Coding**

## SYNTHETIC MESH TAPE/ SLING INSERTION TO TREAT STRESS URINARY INCONTINENCE (SUI) N39.3

### Diagnostic codes for patients admitted for insertion of tape (TVT, TVTO, TOT, mini slings (SIMS))

There are three types of mesh tape to treat SUI with two routes of administration:

I. Retropubic transvaginal tape (TVT) – a mesh tape is introduced through a 1cm incision in the vagina, passed on either side of the urethra as a hammock and exits through the skin either side of the midline above the pubic hair line.
II. Transobturator tape (TVTO, TOT) – a mesh tape is introduced through a 1cm incision in the vagina, passed on either side of the urethra as a hammock and exits through the skin of the right and left inner thighs. Rarely used now because of a higher risk of causing persistent pain.
III. Single incision mini sling procedures (SIMS) are rarely carried out in NI.

All patients admitted for the insertion of transvaginal tapes (TVT, TVTO, TOT, mini slings) have the procedure carried out for the diagnosis of:

**Stress Incontinence (SUI) – N39.3**

As per **User Note** at code **N39.3 Stress Urinary Incontinence,** if the clinician has identified overactive bladder or detrusor muscle hyperactivity within the patient's medical record the coder must assign

code **N32.8 Other specified disorders of bladder** in a secondary position to **N39.3**.

**Procedural codes for Insertion of tape (TVT, TVTO, TOT, mini slings (SIMS))**

| OPCS 4.8 Codes | Narrative |
|---|---|
| **M53.3** | Introduction of retropubic transvaginal tape (TVT) |
| **M53.6** | Introduction of transobturator tape (TOT, TVTO) |
| **M57.1** | Introduction of vaginal tape (SIMS)* |

*Single incision mini sling procedures (SIMS) are rarely if ever be performed in Northern Ireland

## SYNTHETIC MESH TO TREAT PELVIC ORGAN PROLAPSE (POP)

### Diagnostic codes for patients admitted for insertion of synthetic mesh for POP

There are two routes of insertion of synthetic mesh for POP:

Vaginally – a sheet of plastic mesh is placed in the vagina to support weakened tissues. This may be inserted on the front or back wall of the vagina and is sometimes anchored to strong ligaments in the pelvis. These operations have not been used in Northern Ireland since 2015 as they are no longer recommended by NICE for routine use outside research settings in the UK.

Abdominally – mesh can be used from above through the abdomen, rather than through the vagina, to pull up the vagina (colpos) (sacrocolpopexy) or womb (hysterix) (sacrohysteropexy) toward and attach it using synthetic mesh to the backbone (sacrum) to treat pelvic organ prolapse.

POP can be coded from the following range of ICD-10 codes:

- **N81.2 Incomplete uterovaginal prolapse**
- **N81.3 Complete uterovaginal prolapse**
- **N81.4 Uterovaginal prolapse**

POP can be graded by the clinician in the patient's medical record using the Pelvic Organ Prolapse Quantification (POPQ) system using stages 0–4, which does not equate to the degrees stated within category **N81 Female Genital Prolapse** within ICD-10 5th edition. In light of this, NI uro/ gynaecologists have agreed that clinical coders code POP to **N81.4 Uterine prolapse unspecified,** unless the clinician has stated the diagnosis of procidentia, which should be coded to **N81.3 Complete**

**uterovaginal prolapse** or has stated a specific degree of prolapse, which should be coded to the following:

- **N81.2 First or second degree uterine prolapse**
- **N81.3 Third degree uterine prolapse**

In accordance with the exclusion notes in category **N81 Female genital prolapse,** if the clinician has stated that the patient also has any or a combination of:
**female urethrocele, cystocele, vaginal enterocele and /or rectocele**

in combination with POP, these conditions should not be coded separately and only a code for the specific type of POP should be assigned.

**Procedural codes for insertion of synthetic mesh for POP**

| OPCS 4.8 & OPCS 4.9 Codes | Narrative |
|---|---|
| **P23.6*** | Anterior colporrhaphy with mesh reinforcement |
| **P23.7*** | Posterior colporrhaphy with mesh reinforcement |
| **P24.2** | Sacrocolpopexy |
| **P24.5** | Repair of vault of vagina with mesh using abdominal approach |
| **P24.6*** | Repair of vault of vagina with mesh using vaginal approach |
| **Q54.4** | Suspension of uterus using mesh |
| **Q54.5** | Sacrohysteropexy |

**NB:** Codes within category **P22 Repair of prolapse of vagina and amputation of cervix uteri** are rarely performed historic procedures which would never be carried out using mesh.

***P23.6 Anterior colporrhaphy with mesh reinforcement – Not carried out in NI from March 2015**

***P23.7 Posterior colporrhaphy with mesh reinforcement – Not carried out in NI from March 2015**

***P24.6 Repair of vault of vagina with mesh using vaginal approach – Not carried out in NI from March 2015**

**Q54.6 Infracoccygeal hysteropexy** is not carried out in NI

## MESH/TAPE REPAIR OR REMOVAL

### Diagnostic codes for patients admitted for repair or removal of tape or mesh

The following ICD-10 diagnostic code should be assigned to show that a patient has been admitted for the removal (partial/total) or the repair of mesh or tape:

**T83.4 Mechanical complication of other prosthetic device, implant and graft in genital tract**

The mechanical complication could include any of the following:

- Contraction: Shrinkage or reduction in size.
- Prominence: Parts that project beyond the surface(i.e. no penetration).
- Penetration: Piercing or entering(i.e. the vagina).
- Separation: Physically disconnected (e.g. vaginal epithelium).
- Exposure: A condition of displaying, revealing, exhibiting or making accessible (e.g. mesh exposure).
- Extrusion: Passage gradually out of a body structure or tissue.
- Perforation: Abnormal opening into a hollow organ or viscus.

Patients who are admitted for the removal or repair of tape/mesh may have a combination of conditions that has resulted in the need to have the tape or mesh either partially or completely removed or recovered due to exposure, extrusion separation or dehiscence. Women could be experiencing any or a combination of the following:

- Dysuria
- Haematuria
- Infection
- Pain
- Fistulae
- Rectal bleeding
- Sexual difficulty/dyspareunia

One or a combination of the following ICD-10 codes should be assigned **in addition** to **T83.4 Mechanical complication of other prosthetic device, implant and graft in genital tract** when the clinician has documented any of the above conditions in relation to the removal or repair of mesh/tape:

- **T83.6 Infection and inflammatory reaction due to prosthetic device, implant and graft in genital tract**
- **T83.8 Other complications of genitourinary prosthetic devices, implants and grafts**, which includes the following conditions:
  - Embolism
  - Fibrosis
  - Haemorrhage
  - Pain
  - Stenosis
  - Thrombosis

- **R30.0 Dysuria & Y83.1 Surgical operation with implant of artificial internal device**
- **N94.1 Dyspareunia & Y83.1 Surgical operation with implant of artificial internal device**
- **K62.5 Haemorrhage of anus and rectum & Y83.1 Surgical operation with implant of artificial internal device**

- Haematuria will be coded depending on the description of the haematuria by the responsible consultant:

    - **R31.X Haematuria & Y83.1 Surgical operation with implant of artificial internal device**
    - **N02.- Persistent haematuria (4th character will classify morphological changes –** *see table below*) **Y83.1 Surgical operation with implant of artificial internal device**
    - **N02.- Intermittent haematuria (4th character will classify morphological changes –** *see table below*) **Y83.1 Surgical operation with implant of artificial internal device**
    - **N02.- Recurrent haematuria (4th character will classify morphological changes –** *see table below*) **Y83.1 Surgical operation with implant of artificial internal device**

| Fourth Character | Morphological Changes |
|---|---|
| **0** | Minor glomerular abnormality |
| **1** | Focal and segmental glomerular lesions |
| **2** | Diffuse membranous glomerulonephritis |
| **3** | Diffuse mesangial proliferative glomerulonephritis |
| **4** | Diffuse endocapillary proliferative glomerulonephritis |
| **5** | Diffuse mesangiocapillary glomerulonephritis |
| **6** | Dense deposit disease |
| **7** | Diffuse crescentic glomerulonephritis |
| **8** | Other |
| **9** | Unspecified |

- **N82.- Fistulae involving female genital tract (4th character is dependent on the site of the fistulae –** *see table below*) **& Y83.1 Surgical operation with implant of artificial internal device**

| Fourth Character | Site of Fistula |
|---|---|
| **0** | Vesicovaginal fistula |
| **1** | Other female urinary-genital tract fistulae |
| **2** | Fistula of vagina to small intestine |
| **3** | Fistula of vagina to large intestine |
| **4** | Other female intestinal-genital tract fistulae |
| **5** | Female genital tract-skin fistulae |
| **8** | Other female genital tract fistulae |
| **9** | Female genital tract fistula, unspecified |

## Procedural codes for the removal (partial/total) or repair of mesh/tape

| OPCS 4.8 Codes | Narrative |
|---|---|
| **M53.4** | Total removal of tension-free vaginal tape (TVT) |
| **M53.5** | Partial removal of tension-free vaginal tape (TVT) |
| **M53.7** | Total removal of transobturator tape (TVTO/ TOT) |
| **M53.8 & Y25.2** | Over-sewing of exposed synthestic mesh from previous insertion of TVT/TOT/TVTO |
| **M57.2** | Total removal of vaginal tape (SIMS)* |
| **M57.3** | Partial removal of vaginal tape (SIMS)* |
| **M57.4** | Partial removal of transobturator tape (TOT/ TVTO) |
| **P23.8 & Y25.2** | Over-sewing of exposed synthetic mesh from previous vaginal prolapse repair (POP) |
| **P24.8 & Y25.2** | Over-sewing of exposed prosthetic mesh from previous vaginal vault prolapse repair (POP) |
| **P28.1** | Total removal of prosthetic material from previous repair of vaginal prolapse (POP) |
| **P28.2** | Partial removal of prosthetic material from previous repair of vaginal prolapse (POP) |
| **P30.1** | Total removal of prosthetic material from previous repair of vaginal vault prolapse (POP) |
| **P30.2** | Partial removal of prosthetic material from previous repair of vaginal vault prolapse (POP) |
| **Q54.7** | Total removal of prosthetic material from previous suspension of uterus |
| **Q54.8 & Y25.2** | Over-sewing of exposed prosthetic mesh from previous suspension of uterus\ |
| **Q57.1** | Partial removal of prosthetic material from previous suspension of uterus |

* Single incision mini sling (SIMS) procedures are rarely if ever performed in Northern Ireland

## OPCS 4.9 Guidance from 1 September 2020

For patients discharged from 1 September 2020 the following codes can be assigned in a secondary procedural position to identify the type of mesh inserted:

| OPCS 4.9 code | Narrative |
|---|---|
| **Y28.1** | Insertion of synthetic mesh into organ NOC |
| **Y28.2** | Insertion of biological mesh into organ NOC |
| **Y28.3** | Insertion of composite mesh into organ NOC |
| **Y28.4** | Insertion of mesh into organ NOC |
| **Y28.8** | Other specified mesh |
| **Y28.9** | Unspecified |

The following OPCS 4.9 codes can be assigned in a secondary procedural position to a body system chapter procedural code for the removal of mesh where the narrative of the code does not state if the procedure was for complete or partial removal:

| OPCS 4.9 code | Narrative |
|---|---|
| **Y26.6** | Partial removal of mesh from organ NOC |
| **Y26.7** | Total removal of mesh from organ NOC |

### Specific queries and grouping of codes

It was agreed that codes should be grouped to facilitate the running of queries in relation to mid-urethral sling surgery and operations for pelvic organ prolapse. These groups should help us better identify those patients who have required further surgery for mesh related complications. It is hoped this will give us a more accurate picture of re-operation rates and mesh removal activity

### Removal of a Transvaginal Tape sling (TVT)

| OPCS 4.8 Codes | Narrative |
|---|---|
| **M53.4** | Total removal of tension-free vaginal tape TVT |
| **M53.5** | Partial removal of tension-free vaginal tape TVT |

## Removal of a transobturator tape sling (TVTO, TOT)

| OPCS 4.8 Codes | Narrative |
|---|---|
| **M53.7** | Total removal of transobturator tape TVTO |
| **M57.4** | Partial removal of transobturator tape TVTO |

## Removal of a single incision mini sling (SIMS)

| OPCS 4.8 Codes | Narrative |
|---|---|
| **M57.2** | Total removal of vaginal tape (SIMS) |
| **M57.3** | Partial removal of vaginal tape (SIMS) |

## Oversewing of a vaginal mesh exposure following mesh tape sling surgery

| OPCS 4.8 Codes | Narrative |
|---|---|
| **M53.8 & Y25.2** | Over-sewing of exposed synthetic mesh from previous insertion of TVT/TOT/TVTO |

## Removal of mesh for POP

| OPCS 4.8 Codes | Narrative |
|---|---|
| **P28.1** | Total removal of prosthetic material from previous repair of vaginal prolapse |
| **P28.2** | Partial removal of prosthetic material from previous repair of vaginal prolapse |
| **P30.1** | Total removal of prosthetic material from previous repair of vaginal vault prolapse |
| **P30.2** | Partial removal of prosthetic material from previous repair of vaginal vault prolapse |
| **Q54.7** | Total removal of prosthetic material from previous suspension of uterus |
| **Q57.1** | Partial removal of prosthetic material from previous suspension of uterus |

## Oversewing of a vaginal mesh exposure following POP surgery

| OPCS 4.8 & 4.9 Codes | Narrative |
|---|---|
| **P23.8 & Y25.2** | Over-sewing of exposed prosthetic mesh from previous vaginal prolapse repair |
| **P24.8 & Y25.2** | Over-sewing of exposed prosthetic mesh from previous vaginal vault prolapse repair |
| **Q54.8 & Y25.2** | Over-sewing of exposed prosthetic mesh from previous suspension of uterus |

## Conclusion

It is the responsibility of the clinical coder to seek clarification from the responsible clinician if:

- There is insufficient information within the patient's medical record
- Ambiguous language has been stated
- Differing diagnosis(es) or procedure(s) has been recorded across the episode/spell
- They do not understand the medical/surgical terminology recorded
- The diagnosis/procedure carried out has no current clinical coding guidance

The clinician coder should also seek assistance from the Regional Clinical Coding team if:

- This guidance does not cover a diagnosis or procedure they encounter when coding
- They require clarity on how to apply this guidance

**Appendix I**

## MESH Patient Information and Consent

### Aim

To improve services for women requiring surgery for urinary incontinence and pelvic organ prolapse involving (amongst others) MESH procedures

### Objectives

To agree scope and scale of the work required

To establish baselines and reporting arrangements

To develop regionally agreed arrangements for patient information and consent

To find meaningful ways of patient engagement

To contribute to a final report and recommendations for future work

### Modus operandi

To meet approximately monthly until present objectives are achieved

To advise at that point how the working group might change

To produce a brief record of meetings

To agree and share agenda and papers a week before meetings

To undertake work between meetings to achieve objectives

To collaborate with working group members and others relevant in the context of this project

To maintain confidentiality and communicate respectfully and appropriately within and outwith meetings

**Appendix J**

**Thursday 24 May 2018 - Meeting to discuss MESH leaflets**

**Skeffington Room, Clotworthy House, Antrim Castle Gardens, 10.00- 13.00**

1. **Minutes**

   Christine provided an update regarding communication with the clinical director of UCHL, PHA release of updated FAQs, progress with the MESH report, procurement of 3D scanner and current state of the MESH centre in Belfast.

2. **Leaflets were discussed and comments taken (see below).**

| Leaflet | Comments |
|---|---|
| **Comparison of treatment options for Stress Urinary Incontinence in women (BAUS 16/174 April 2017)** | • Mid-urethral tapes need to reflect difference between TVT and TVTO- does latter need removed due to higher complication rate?<br>• Unclear complication rates- seem low, need to spell out which ones are common and should make reference to emerging evidence.<br>• No reference to potential permanent pain and its potentially detrimental effects on quality of life under complications<br>• Fascial/ autologous sling section does not spell out what material/ human tissue is used.<br>• Requires a glossary of terms |
| **Colposuspension for Stress Urinary** | • No particular comments |

| Leaflet | Comments |
|---|---|
| **Incontinence (BAUS 17/146 April 2017)** | |
| **Autologous Sling Procedure for Stress Urinary Incontinence (BAUS 17/145 June 2017)** | • No particular comments |
| **Synthetic mid-urethral tapes for Stress Urinary Incontinence (BAUS 16/153 June 2017)** | • Inappropriate use of word 'ribbon' to describe MESH. Visual imagery conjured is not reflective of the material used; should be replaced with something like:' the tape is made out of plastic mesh'.<br>• Statistics describing risks of complication are unclear.<br>• No reference to potential for permanent nerve pain beyond pelvic area affecting legs or becoming widespread<br>• Consider use of word 'erosion' when describing effects of 'migration' of tape.<br>• Explain 'inadvertent injury at time of surgery' especially with TVTO.<br>• Complex terminology used- aim for recommended reading age 9 in all patient information |

| Leaflet | Comments |
|---|---|
| | • Provide advice regarding action to take and when to contact a health professional post-operatively if experiencing symptoms, e.g. 'what to do if your recovery is not as expected'.<br>• Advise patients to keep the leaflet for future reference<br>• Consider incorporating a flow chart of what to expect after the initial consultant appointment. |
| **Synthetic Vaginal Mesh Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women (NHS Version 24 May 2017)** | • This leaflet has a glossary, is well presented and easy to follow; having 'NHS' on it reassures patients who feel it has been sanctioned by the health service.<br>• Need to provide a local contact number post-operatively for patient use in case of concerns; leave space for this to be entered.<br>• Scottish reference to not routinely offering TVTO also applies to NI.<br>• Alternative treatment options should be mentioned earlier in the leaflet- currently on pg 8.<br>• Review and update common and uncommon complications including persistent pain in light of emerging evidence (pg 11) |

| Leaflet | Comments |
|---|---|
| | • Update self-help groups to include Sling the Mesh NI, Mesh Ireland, TVT Meshed up Mums, Sling the Mesh UK (pg 14) |

**3. FAQs were discussed and comments taken;**

- Concern regarding variation of statistics needs to be addressed (Q6)
- Clarification required that equipment, such as translabial scanner, has not yet been bought
- Clarification required whether patients are entitled to NHS care after having private treatment for MESH (Q19)

**4. Next Steps**

- Finalise recommendations for BAUS and NHS leaflet changes and include in Mesh Review report
- Forward comments to BAUS and explore if NHS leaflet can be adapted for HSCNI.