Llywodraeth Cymru
Welsh Government

# WRITTEN STATEMENT
# BY
# THE WELSH GOVERNMENT

**TITLE** **Management of Urinary Incontinence in Women**

**DATE** **18 February 2014**

**BY** **Mark Drakeford AM, Minister for Health and Social Services**

Jocelyn Davies AM raised concerns in the Assembly on 14 January 2014 about adverse events connected to surgery for bladder problems using tension-free vaginal tapes (TVTs) and meshes. I undertook to provide a Written Statement on this matter.

Urinary incontinence (UI) is a common symptom that can affect women of all ages, with a wide range of severity and nature. While rarely life-threatening, incontinence may seriously influence the physical, psychological and social wellbeing of affected individuals.

The National Institute for Health and Care Excellence (NICE) first published guidance on the management of urinary incontinence in women in 2006 and updated guidance (clinical Guideline CG171) was published in September 2013. This guidance is supported by two sets of interventional procedures guidance:

- on surgical repair of vaginal wall prolapse using mesh (IPG267) and
- sacrocolpopexy using mesh for vaginal vault prolapse repair (IPG283).

The Medical Healthcare products Regulatory Agency (MHRA) commissioned York University to review the published literature on the most frequently reported adverse events in the light of concerns expressed by patient groups about TVT and mesh procedures. York University Health Economics Consortium reported in 2012 on the rates of common adverse events associated with TVTs for the treatment of stress urinary incontinence (SUI), and meshes for pelvic organ prolapse (POP).

In summary the report confirmed;

- that adverse event rates associated with the various surgical techniques using TVTs for SUIs are generally in the range 1-3% (9% for deterioration in sexual function for one technique); and
- adverse event rates for surgical techniques using vaginal meshes for POP are in the range 2-6% for most outcomes, but 14-15% for deterioration in sexual function.

The report concluded that interpretation of these findings was not straightforward as many patients experience symptoms such as sexual problems before surgery, and rates of adverse events for surgery not using implants are believed to be as high as or higher than those using implants. Further information was felt to be required and an ongoing trial looking at evidence of the relative safety of prolapse repairs using native tissue repair and mesh implants, which is due to report in 2014.

A letter to Medical Directors in NHS Wales was issued by Dr Heather Payne, Senior Medical Officer, in January 2013 regarding surgical management of SUI and POP. This letter drew attention to the York University report recommendations and the need for compliance with existing NICE and professional guidance on the safe and appropriate use of these devices.

In response to these earlier concerns, the MHRA, working with the two professional associations – the British Society for Urological Gynaecology (BSUG) and the British Association of Urological Surgeons (BAUS), developed a range of materials for clinicians and patients, including patient information leaflets, and a set of questions which patients should ask their surgeons when considering possible surgery. These are available on the MHRA website.

The MHRA's current view is that for the vast majority of women, mesh and tape implants are a safe and effective operation, but as with all surgery, there is an element of risk. While a small number of women have experienced distressing and severe effects, the current evidence shows that when these products are used correctly they can help with the very distressing symptoms of these conditions and as such the benefits still outweigh the risks.

The MHRA continues to encourage voluntary reporting of adverse incidents from all health care workers, as well as carers, patients and members of the public, although it is acknowledged that there is considerable under reporting of complications. There are currently no plans in place to introduce mandatory reporting of medical device adverse incidents by health care professionals; however, the situation is under constant review to ensure that appropriate systems are in place to facilitate the reporting of adverse incidents from all sources. Attached at Annex 1 is the data available in relation to the number of these procedures undertaken but I would draw your attention to the limitations of the data.

NHS England have recently (December 2013) issued further advice to clinicians on this issue drawing their attention to updated guidance and summarising a number of actions highlighted below and this updated guidance is currently being issued to NHS Medical Directors within Wales, covering the need to demonstrate good clinical practice in:

1. **Consent**: standardisation of all consenting processes to comply with up to date evidence and risk management at all levels from individual, local NHS and also at UK level.

2. **Audit**: compliance with NICE recommendations that mesh insertion should be part of regular audit; and that **all** procedures and incontinence operations, but particularly those involving mesh, are recorded on a recognised database.

3. **Adverse event reporting**: reporting of all adverse events involving Mesh used operatively to the Medicines and Healthcare Products Regulatory Agency (MHRA)

4. **Surgery for removal of mesh**: demonstrating that any surgery for removal of TVTs or prolapse mesh, or repeat surgery for incontinence or prolapse is to be performed in units which can demonstrate relevant levels of specialist care (through audited volume and outcome of surgery)

## Annex 1

**Finished consultant episodes for women who have received a primary or secondary operative procedure for the insertion of transvaginal mesh, transobturator tape, transvaginal slings and transvaginal tape.**

| Procedure | 2007-08 | 2008-09 | 2009-10 | 2010-11 | 2011-12 | 2012-13 |
|---|---|---|---|---|---|---|
| Insertion of transvaginal mesh or Insertion of transvaginal sling | 45 | 29 | 20 | 22 | 24 | 16 |
| Insertion of transobturator tape | 306 | 355 | 405 | 306 | 284 | 265 |
| Insertion of transvaginal tape | 388 | 398 | 322 | 329 | 310 | 365 |

***Source*:** PEDW (Patient Episode Database Wales), NWIS (NHS Wales Informatics Service).
***Notes*:**

- Care should be taken when comparing the figures in this table to data published by other countries as the procedure codes used may vary.
- Insertion of transvaginal mesh and insertion of transvaginal sling are combined together as clinical coding advice says there is no way of identifying them separately.
- Relates to activity in Welsh NHS Hospitals and Welsh NHS commissioned activity in the independent sector.
- The figures do not represent the number of different patients, as a person may have more than one episode of care within the same stay in hospital or in different stays in the same year.
- A different version of the OPCS Classification of Interventions and Procedures codes was used prior to 2007-08 in Wales and therefore data prior to 2007-08 is not comparable.
- Codes used for the individual groups are the following:
  Insertion of transvaginal mesh or Insertion of transvaginal sling – M538
  Insertion of transobturator tape – M536
  Insertion of transvaginal tape – M533

**Finished consultant episodes for women with a primary or secondary operative procedure for the removal of transobturator tape and transvaginal tape.**

| Procedure | 2007-08 | 2008-09 | 2009-10 | 2010-11 | 2011-12 | 2012-13 |
|---|---|---|---|---|---|---|
| Removal of transobturator tape | 2 | 2 | 5 | 3 | 4 | 4 |
| Removal of transvaginal tape | 25 | 22 | 20 | 17 | 18 | 22 |

***Source*:** PEDW (Patient Episode Database Wales), NWIS (NHS Wales Informatics Service).
***Notes*:**

- Care should be taken when comparing the figures in this table to data published by other countries as the procedure codes used may vary.
- Relates to activity in Welsh NHS Hospitals and Welsh NHS commissioned activity in the independent sector.
- The figures do not represent the number of different patients, as a person may have more than one episode of care within the same stay in hospital or in different stays in the same year.
- A different version of the OPCS Classification of Interventions and Procedures codes was used prior to 2007-08 in Wales and therefore data prior to 2007-08 is not comparable.
- Codes used for the individual groups are the following:
  Removal of transobturator tape – M537
  Removal of transvaginal tape - M534, M535

Between 2005 and 2013, the Medicines and Healthcare products Regulatory Agency (MHRA) has received only 1 report where the contact address was given in Wales (in 2011) concerning adverse events relating to vaginal tape and mesh implants.

***Number of patient safety incidents relating to mesh used in gynaecological procedures reported to the National Reporting and Learning System (year of occurrence by reported degree of harm)***

| | *No harm* | *Low* | *Moderate* | Severe | *Total* |
|---|---|---|---|---|---|
| 2008 | 1 | 0 | 0 | 0 | 1 |
| 2009 | 0 | 1 | 1 | 1 | 3 |
| 2010 | 1 | 2 | 0 | 0 | 3 |
| 2011 | 2 | 1 | 0 | 0 | 3 |
| 2012 | 3 | 0 | 0 | 0 | 3 |
| 2013 | 1 | 2 | 0 | 0 | 3 |
| Total | 8 | 6 | 1 | 1 | 16 |

*Source*: NRLS

***Notes:***

- Degree of harm is subjective to the reporter who may not follow NRLS guidelines and is sometimes mistaken for potential rather than actual degree of harm to patient