Annex G: Pelvic mesh Supporting Information

Contents

Introduction

1. The IMMDS Review Terms of Reference include abdominal and vaginal pelvic mesh procedures used in the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP). The following information is provided as background and to supplement the main report.

Types of incontinence and non-mesh and mesh treatments:

1. There are several types of urinary incontinence[1], including:

    - Stress incontinence – when urine leaks out when the bladder is under pressure; for example, during coughing or laughing. This can be due to a weakness in the pelvic floor muscles (which keep the bladder closed), the urethra or the ligaments that support the urethra[2].
    - Urge incontinence – when a sudden, intense urge to pass urine is felt, and urine leaks during this time, or soon afterwards.
    - Overflow incontinence (chronic urinary retention) – when the bladder is unable to fully empty, which causes frequent leaking.
    - Total incontinence – when the bladder can't store any urine at all, which causes a constant passing of urine or frequent leaking.

2. It is also possible to have a mixture of both stress and urge urinary incontinence[1].

Conservative non-surgical treatments for SUI

[1] NHS, Overview - Urinary incontinence, available online at: https://www.nhs.uk/conditions/urinary-incontinence/

[2] P. Petros, U. I. Ulmsten, An integral theory of female urinary incontinence. Experimental and clinical considerations. *Acta obstetricia et gynecologica Scandinavica. Supplement* **153**, 7-31 (1990).

3. Lifestyle changes. These include:

    - being a healthy weight
    - avoiding activities that cause leaks, such as lifting heavy objects and high-impact exercise, such as trampolining
    - reducing caffeine intake as caffeine is a diuretic
    - using protective pads and clothing.

4. Pelvic floor physiotherapy: Exercises to strengthen the pelvic floor muscles and reduce symptoms for SUI. Exercises and physiotherapy can include biofeedback, electrical stimulation, vaginal cones and bladder training as appropriate for the individual. This is recommended by NICE before any surgery is considered.

5. Medications: The medication used will depend on the type of incontinence experienced.

6. Bulking agent injections: A procedure used to treat stress urinary incontinence. The procedure involves injecting a bulking agent into the wall of the urethra, this narrows the urethra, helping the urethra to form an effective seal and allowing the bladder to hold urine[3]. Several bulking agents are used in the UK[4].

Surgical treatments for Incontinence

TVT (Tension-free vaginal tape):

7. The TVT procedure is a form of low-tension urethropexy[5] (a procedure that provides support to the urethra). It is used to treat SUI. The traditional TVT procedure involves inserting a mesh strip (sometimes called a tape) through a small cut in the front wall

[3] IUGA, Urethral bulking for stress urinary incontinence – A Guide for Women, 2013, available online at: https://thepelvicfloorsociety.co.uk/images/uploads/eng_urebulk.pdf
[4] NICE, 2005, Intramural urethral bulking procedures for stress urinary incontinence in women Interventional procedures guidance [IPG138], available online at: https://www.nice.org.uk/guidance/ipg138/chapter/2-The-procedure

[5] NICE, Final Appraisal Determination – Tension-free vaginal tape (Gynecare TVT) for stress incontinence, January 2003, available online at: https://www.nice.org.uk/guidance/ta56/documents/final-appraisal-determination-tension-free-vaginal-tape-gynecare-tvt-for-stress-incontinence2

of the vagina. It is then introduced through the retropubic space (the space behind the pubic bone) and passed under the urethra to support it. The mesh is secured through two small cuts in the abdominal wall. The mesh strip forms a U-shaped sling around the middle third of the urethra. Due to the strong friction between the mesh tape and the narrow tissue canals created by the procedure, no fixation of the mesh strip is necessary.

8. The rationale for the technology is, according to NICE, based on a controversial idea called the 'integral theory of female urinary incontinence'[5]. This theory proposes that SUI is caused by connective tissue weakness in the vagina, or laxity in supporting ligaments. When the pelvic floor muscles are unable to compensate for this laxity, closure of the urethra is not maintained. It is thought that the tape acts as an artificial ligament in order to support urethral closure[6].

Transobturator mesh placement (TVT-O and TOT)

9. These procedures are similar to the TVT procedure, but the mesh strip is directed through the obturator foramen - rather than through the retropubic space – and out through two incisions in the groin.

10. Two approaches exist; the first is the 'outside-in' or TOT (Transobturator tape) procedure, introduced by Delorme in 2001[7]. The second is the 'inside-out', or TVT-O (Tension-free tape – obturator) procedure, introduced by Leval in 2003[8].

11. The TOT, or 'outside-in' approach involves placement of the tape that is initiated through an incision in the skin, before the mesh is directed through a periurethral incision. The tape sits underneath the midurethra, without tension, running laterally through the obturator membrane to the upper part of the thigh, from outside to inside[9].

12. The TVT-O, or 'inside-out' approach involves the mesh being introduced through an incision in the vagina, through the obturator foramens and out through two groin incisions (inside to outside) using specialised instruments called 'helical passers'.

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[6] P. Petros, U. I. Ulmsten, An integral theory of female urinary incontinence. Experimental and clinical considerations. *Acta obstetricia et gynecologica Scandinavica. Supplement* **153**, 7-31 (1990).
[7] E. Delorme, Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. *Prog Urol* **11**, 1306-1313 (2001).
[8] J. de Leval, Novel Surgical Technique for the Treatment of Female Stress Urinary Incontinence: Transobturator Vaginal Tape Inside-Out. *European urology* **44**, 724-730 (2003).
[9] M. K. Cho *et al.*, Complications Following Outside-in and Inside-out Transobturator-Tape Procedures with Concomitant Gynecologic Operations. *Chonnam Med J* **47**, 165-169 (2011).

(Burch) Colposuspension

13. This is a treatment for SUI which is designed to support the bladder neck (area between the bladder and urethra). The procedure involves securing the area around the bladder neck (the lower part of the front of the vagina) to the back of a ligament behind the pubic bone (Cooper's ligament[10]) using stitches[11]. The procedure is usually performed through an abdominal incision, but can be performed laparoscopically ('keyhole'). Lifting the tissue in this way helps to prevent leakage by supporting the bladder opening at times of downward pressure transmission (eg. exercising and coughing)[12].

Types of prolapse and non-mesh and mesh treatments:

Anterior prolapse (cystocele)

14. Prolapse of the bladder into the front wall of the vagina[13].

Posterior prolapse (rectocele or enterocele)

[10] E. A. Tanagho, Colpocystourethropexy: The Way we do it. *The Journal of Urology* **116**, 751-753 (1976).
[11] Brighton and Sussex University Hospitals Trust, Department of Gynaecology, Burch Colposuspension Patient Information Leaflet, 2018 (updated 2020), available online at: https://www.bsuh.nhs.uk/wp-content/uploads/sites/5/2016/09/Burch-Colposuspension.pdf
[12] BAUS, Colposuspension for Stress Urinary Incontinence (SUI) Patient Information Leaflet, 2018 (updated 2020), available online at: https://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/Colposuspension.pdf
[13] NHS, **Overview** - Pelvic organ prolapse, available online at: https://www.nhs.uk/conditions/pelvic-organ-prolapse/

15. Prolapse of the rectum into the vagina (rectocele)[14] or more rarely, herniation of the small intestine against the vaginal wall (enterocele – more typical in the absence of a uterus e.g. post-hysterectomy).

Uterine prolapse

16. Prolapse of the uterus and cervix down the vaginal canal. Sometimes, the uterus may prolapse so far that it goes past the vaginal opening, this is known as 'procidentia', or third-degree prolapse[14].

Vaginal vault prolapse

17. Prolapse of the top of the vagina (known as the 'vaginal vault') down the vaginal canal. This occurs in women who have previously had a hysterectomy (removal of the uterus)[14].Measures can be taken at the point of hysterectomy to prevent vaginal vault prolapse [15]

Conservative non-surgical treatments for POP

18. Lifestyle changes include:

- being a healthy weight
- eating a high-fibre diet to avoid constipation
- avoiding lifting heavy objects
- avoiding high-impact exercise, such as trampolining
- stopping smoking as it can cause coughing and make the prolapse worse

19. Pelvic floor exercises and physiotherapy to strengthen the pelvic floor muscles and reduce symptoms for POP. This is recommended by NICE before any surgery is considered.

[14] RCOG, 2013, Pelvic Organ Prolapse, Patient Information Leaflet, available online at: https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/gynaecology/pi-pelvic-organ-prolapse.pdf

[15] RCOG/BSUG, 2015, Post-Hysterctomy Vaginal Vault Prolapse, Green top Guide No. 46, available online at: https://www.rcog.org.uk/globalassets/documents/guidelines/gtg-46.pdf

20. Hormone treatment may be used in women with a mild prolapse who are post-menopausal. Oestrogen is applied directly to the vagina and works to ease symptoms of vaginal atrophy such as vaginal dryness or discomfort during sex.

21. Vaginal pessaries are latex or silicone devices that come in various shapes and sizes. They are inserted into the vagina to provide support in moderate to severe prolapses. Vaginal pessaries need to be regularly removed and cleaned. Vaginal pessaries can usually be left in place during intercourse and do not impact on a woman's fertility.

Sacrocolpopexy

22. A procedure used to treat a prolapse of the vaginal vault (top of the vagina). A piece of surgical mesh is attached to the front and back walls of the vagina and then to the sacrum (via stitched or staples) to suspend the top of the vagina or the cervix back into its normal position[16]. This can be performed as an 'open' or 'keyhole' operation.

Sacrohysteropexy

23. A procedure used to treat uterine prolapse. A piece of mesh is attached to the back, or around the lower part of the uterus, with the other end of the mesh being attached to the sacrum[17]. This can be performed as an 'open' or 'keyhole' operation[18].

Sacrospinous fixation

24. A procedure used to treat uterine prolapse or vaginal vault prolapse. It can also be used to treat prolapse of the bladder or bowel to an extent. The procedure involves stitching the top of the vagina (vaginal vault) to the left and/or right sacrospinous

[16] BSUG, 2017, Sacrocolpopexy for Vaginal Vault Prolapse – Patient Information Leaflet, available online at: https://bsug.org.uk/budcms/includes/kcfinder/upload/files/info-leaflets/SCP%20BSUG%20July%202017.pdf

[17] NICE, 2017, Uterine suspension using mesh (including sacrohysteropexy) to repair uterine prolapse Interventional procedures guidance [IPG584], available online at: https://www.nice.org.uk/guidance/ipg584/chapter/3-The-procedure

[18] BSUG, 2017, Sacrohysteropexy for Uterine Prolapse (Womb Prolapse), Patient Information Leaflet, available online at: https://bsug.org.uk/budcms/includes/kcfinder/upload/files/info-leaflets/SHP%20BSUG%20July%202017.pdf

ligament, at the back of the pelvis. The procedure is done through the vagina, so no abdominal incisions are made[19].

Colpocleisis

25. A procedure used to treat severe vaginal prolapse in patients who do not plan to be sexually active in future, as the vagina is effectively closed by the procedure[20]. The procedure involves sewing together the front and back walls of the vagina in order to shorten the vaginal canal. This prevents the vaginal walls from bulging inward and provides support to hold up the uterus.

26. This can be performed as a full or partial procedure. Full colpocloeisis involves complete closure of the vagina, whereas partial colpocleisis is performed if the uterus is present. During partial colpocleisis, a small strip of vaginal skin flanking the vaginal canal is left unstitched to allow drainage of secretions / blood from the uterus or cervix[20].

Colporrhaphy

27. A procedure used to treat both anterior prolapse (cystocele) and posterior prolapse (rectocele). Also known as a 'vaginal repair'. The procedure may be performed on the anterior (front) or posterior (back) walls of the vagina, with the former used to treat cystocele and the latter rectocele. The procedure involves folding over the prolapsed portion of the vagina and suturing it, this strengthens the area[21].

[19] BSUG, 2017, Sacrospinous fixation (SSF) for prolapse of the uterus (womb) or prolapse of the vaginal vault (top of vagina) – Patient Information Leaflet, available online at: https://bsug.org.uk/budcms/includes/kcfinder/upload/files/info-leaflets/SSF%20BSUG%20July%202017.pdf

[20] BSUG, 2017, Colpocleisis (Closing the vagina to treat prolapse) – Patient Information Leaflet, available online at: https://bsug.org.uk/budcms/includes/kcfinder/upload/files/info-leaflets/Colpocleisis%20BSUG%20July%202017.pdf

[21] University College London Hospitals, 2017, Colporrhaphy - An operation for prolapse of the vaginal walls, Patient Information Leaflet, available online at: https://www.uclh.nhs.uk/PandV/PIL/Patient%20information%20leaflets/Colporrhaphy.pdf

Summary of regulatory activity, including NICE guidance

Organisation	Action	Date	Key Content
SERNIP	Fifth meeting[22]	8th January 1998	Fifth meeting of SERNIP, in which Cystourethropexy (using 'In-tac' bone anchors to secure the bladder neck sling) procedure is classified as category Cii
SERNIP	Twelfth meeting[23]	6th October 1999	Intravaginal slingplasty procedure is categorised as "C" (Safety and efficacy not proven), with a rider to await the results of randomised control trials that were ongoing at the time.
SERNIP	Thirteenth meeting[24]	12th January 2000	The chairman reported that Ethicon had challenged the classification of tension free urethropexy, with their main concern being affected sales in Europe. In response to the challenge, a Review Group was set up to consider the procedure and consider further reports submitted by the company. The group comprised two members of the SERNIP Advisory Committee and an independent expert from the British Association of Urological Surgeons.

[22] SERNIP, advisory committee minutes, provided by NICE in response to FOI request EH95323, available at: https://www.whatdotheyknow.com/request/clinical_guidance_for_polypropyl#incoming-1236732
[23] SERNIP, advisory committee minutes, provided by NICE in response to FOI request EH95323, available at: https://www.whatdotheyknow.com/request/clinical_guidance_for_polypropyl#incoming-1236732
[24] SERNIP, advisory committee minutes, provided by NICE in response to FOI request EH95323, available at: https://www.whatdotheyknow.com/request/clinical_guidance_for_polypropyl#incoming-1236732

			The group's overall view was that, on the grounds of extensive usage, the categorisation of the procedure should be upgraded. Valid safety and efficacy data in a further 268 cases from various conference proceedings provided by Ethicon bought the total cases known to SERNIP to 553. Although this was all observational data, the committee felt that efficacy had been sufficiently demonstrated. Reclassification was from 'C' to 'A'. The committee expressed the hope that the new randomised control trials would uphold this conclusion. Ethicon provided 4 additional papers which had not already been reviewed. Two were duplicate publications (in whole or part) and 2 were excluded for other reasons. There were also 30 conference abstracts, most of which consisted of incomplete or uninterpretable results. Those with only subjective outcome or follow-up of less than six months were excluded, leaving 6 conference abstracts. This included 268 patients with an 86% objective cure at 6 months or more. Bladder perforation occurred in 7% and de novo detrusor instability in 3%. Ethicon made the following response to this event: "Ethicon advised that that there were peer reviewed papers on TVT in the public domain at the time including the Ulmsten and Petros papers concerning the design and development of TVT, Professor Ulmsten's 1996 single center study and the TVT 1998 multicenter study, as well as: 1. Nilsson CG. The tension free vaginal tape procedure (TVT) for treatment of female urinary incontinence. A minimal invasive surgical procedure. Acta Obstet Gynecol Scand Suppl 1998;168:34-7

			2. Wang AC, Lo TS. Tension-Free Vaginal Tape: A Minimally Invasive Solution to Stress Urinary Incontinence in Women. J Reprod Med 1998;43:429-434 3. Paparella P, De Santis L. A study of tension-free vaginal tape (TVT) in association with Lahodny's urethrocystopexy for the surgical treatment of stress urinary incontinence in patients with severe urethrocystocele. Urogynaecologia Int J 1999;13(2):65-70 4. Olsson I, Kroon U. A Three-Year Postoperative Evaluation of Tension-Free Vaginal Tape. Gynecol Obstet Invest 1999;48(4):267-9 5. Ulmsten U, Johnson P, Rezapour M. A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. Br J Obstet Gynaecol 1999 Apr;106(4):345-50 6. Maltau JM, Verelst M, Holtedahl KA, Due J. A new minimally invasive surgical method for stress incontinence in women. Tidsskr Nor Laegeforen 1999 Jun 20;119(16):23425 7. Primicerio M, De Matteis G, Montanino Oliva M, Marceca M, Alessandrini A, Caviezel P, Tocci A. Use of the TVT (Tension-free Vaginal Tape) in the treatment of female urinary stress incontinence. Preliminary results. Minerva Ginecol. 1999 Sep;51(9):3558”
NICE	Final Appraisal Determination Tension-free vaginal tape (Gynecare TVT)	January 2003	Guidance: The tension-free vaginal tape (TVT) procedure is recommended as one of a range of surgical options for women with uncomplicated urodynamic stress incontinence in whom conservative management has failed. In making the decision to use TVT, the patient should be fully informed of the advantages and drawbacks of the relevant surgical procedures. The considerations should include:

	for stress incontinence[25]		- the advantages of a minimal-access technique, set against the disadvantage of the absence of data on long-term effectiveness - whether the woman is likely to have children subsequently - whether the procedure will be used in conjunction with another procedure, such as vaginal hysterectomy or repair of prolapse. The TVT procedure should be performed only by surgeons who have received appropriate training in the technique, and who regularly carry out surgery for stress incontinence in women. Clinical/cost effectiveness: NICE summarise available evidence on clinical effectiveness by stating that "the TVT procedure appears have similar effectiveness to the main alternative therapies in the surgical management of stress urinary incontinence. It is associated with a shorter hospital stay than standard methods, such as open colposuspension or traditional sling procedures" NICE summarise available evidence on cost effectiveness by stating that "although the cost of the materials used in the TVT procedure is higher than for colposuspension, the overall cost is lower because of the shorter associated hospital stay. The TVT procedure appears to be cost effective relative to colposuspension."

[25] NICE, 2003, Final Appraisal Determination – Tension-free vaginal tape (Gynecare TVT) for stress incontinence, available at: https://www.nice.org.uk/guidance/ta56/documents/final-appraisal-determination-tension-free-vaginal-tape-gynecare-tvt-for-stress-incontinence2

			The Committee noted that this procedure requires that surgeons be adequately trained. The amount of training required by each individual surgeon varies according to his or her experience in urogynaecological surgery. Expertise in identifying patients for whom the procedure is appropriate is also necessary. Recommendations for further research: Further information on the long-term effectiveness and complication rate of the TVT procedure is required. It is recommended that observational data on effectiveness and safety of the procedure are collected over a period of 10 years or more. Preferably this should be nationally coordinated in the form of a registry of audit data to include both the numbers of procedures carried out and measures of outcome and adverse events.
NICE	Guideline CG40: Urinary incontinence: the management of urinary incontinence in women[26]	October 2006	NICE make the following recommendations, related to mesh treatment for SUI: - A trial of supervised pelvic floor muscle training of at least 3 months' duration should be offered as first-line treatment to women with stress or mixed UI. - Bladder training lasting for a minimum of 6 weeks should be offered as first line treatment to women with urge or mixed UI.

[26]NICE, Guideline CG40: Urinary incontinence: the management of urinary incontinence in women 2006, available online at: https://www.sauga.org.za/content/images/Nice%20incontinence.pdf

			- Pelvic floor muscle training should be offered to women in their first pregnancy as a preventive strategy for UI. - Any woman wishing to consider surgical treatment for UI should be informed about the benefits and risks of surgical and non-surgical options. Counselling should include consideration of the woman's child-bearing wishes. - Retropubic mid-urethral tape procedures using a 'bottom-up' approach with macroporous (type 1) polypropylene meshes are recommended as treatment options for stress UI where conservative management has failed. Open colposuspension and autologous rectus fascial sling are the recommended alternatives when clinically appropriate. - Synthetic slings using a retropubic 'top-down' or a transobturator foramen approach are recommended as alternative treatment options for stress UI if conservative management has failed, provided that women are made aware of the lack of long-term outcome data. - Synthetic slings using materials other than polypropylene that are not of a macroporous (type 1) construction are not recommended for the treatment of stress UI.

			- Surgery for UI should be undertaken only by surgeons who have received appropriate training in the management of UI and associated disorders or who work within a multidisciplinary team with this training, and who regularly carry out surgery for UI in women. - Any woman wishing to consider surgical treatment for UI should be informed about the benefits and risks of surgical and non-surgical options. Counselling should include consideration of the woman's child-bearing wishes. - Surgery for UI or OAB in women should be undertaken only by surgeons who carry out a sufficient case load to maintain their skills. An annual workload of at least 20 cases of each primary procedure for stress UI is recommended. - A national audit of continence surgery should be undertaken. - Surgeons undertaking continence surgery should maintain careful audit data and submit their outcomes to national registries such as those held by the British Society of Urogynaecology (BSUG) and British Association of Urological Surgeons Section of Female and Reconstructive Urology (BAUS-SFRU).
FDA	Public Health Notification: Serious	20th October 2008	The public health notification is designed to alert Healthcare Practitioners to complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse

	Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence[27]		(POP) and Stress Urinary Incontinence (SUI). *"Although rare, these complications can have serious consequences".* The PHN contains recommendations that Physicians should: - Obtain specialised training for each mesh placement technique, and be aware of its risks. - Be vigilant for potential adverse events from the mesh, especially erosion and infection. - Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations. - Inform patients that implantation of surgical mesh is permanent, and that some complications may require additional surgery that may or may not correct the complication. - Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring of the vaginal wall, and narrowing of the vagina. - Provide patients with a written copy of the patient labelling from the surgical mesh manufacturer, if available. Reporting of adverse events related to medical devices to the FDA is encouraged also.
Health Canada	Notice to Hospitals[28]	4th Februar y 2010	Reported complications associated with the use of transvaginally-placed mesh for the treatment of SUI and POP include erosion (vaginal, urethral), pain including dyspareunia, infection as well as perforations and other injuries to adjacent organs including the bowel,

[27] FDA, 2008, Public health notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence, available online at: http://www.amiform.com/web/documents-risques-op-coelio-vagi/fda-notification-about-vaginal-mesh.pdf

[28] Surgical Mesh - Complications Associated with Transvaginal Implantation of Surgical Mesh for the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse - Recalls and safety alerts

			bladder and blood vessels. Risk factors associated with these complications are not completely understood but may relate to both patient-specific factors such as age, overall health status, oestrogen status and a history of previous surgery in the area as well as procedure-specific factors such as surgical technique and route of mesh placement. Required treatment for these adverse events varies depending on the complication but can involve surgical intervention including complete mesh removal. In light of this and other available information, Health Canada recommends the following: • Review the labelling of relevant devices, especially sections concerning warnings, precautions and adverse reactions. • Inform patients during the presurgical consultation of adverse events that may occur. Though transvaginal implantation of surgical mesh is generally considered permanent, patients should be aware of the possible need for additional surgical procedures that may not always fully correct some potential complications. • Be observant both intraoperatively and postoperatively for signs of any complications associated with transvaginal mesh placement. • Be aware of and/or get training on proper case selection, initial implantation procedure and management of complications. • Any cases of serious or unexpected adverse incidents in patients implanted with transvaginally-placed surgical mesh should be reported to Health Canada

FDA	Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse[29]	July 2011	The FDA determined that: - serious adverse events are NOT rare, contrary to what was stated in the 2008 PHN. - transvaginally placed mesh in POP repair does NOT conclusively improve clinical outcomes over traditional non-mesh repair. Based on evaluation of adverse event reports and assessment of the scientific literature, the FDA has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk. In particular, these products are associated with serious adverse events, including vaginal mesh erosion, a complication which can require multiple surgeries to repair and may result in continued sequelae (e.g., pain) even after mesh removal. Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair, particularly for transvaginal apical and posterior repair. While the literature suggests an anatomic benefit to anterior repair with mesh augmentation, this anatomic benefit may not result in superior clinical outcomes, and the associated risk of adverse events should be considered. The FDA conducted a search of the Manufacturer and User Device Experience (MAUDE) database for medical device reports (MDRs) of adverse events associated with all

[29] FDA, 2011, Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse, available online at: http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf

			urogynaecologic surgical mesh products received from January 1, 2005 - December 31, 2010. The search identified 3,979 reports of injury, death, and malfunction. Among the 3,979 reports, 2,874 reports were received in the last 3 years (January 1, 2008 - December 31, 2010), and included 1,503 reports associated with POP repairs and 1,371 associated with SUI repairs. The number of MDRs associated with POP repairs increased by more than 5-fold compared to the number of reports received in the previous 3 years (January 1, 2005 - December 31, 2007). Recommendations for patients: • Be aware of the risks associated with transvaginal POP repair. • Know that having a mesh surgery may increase the risk for needing additional surgery due to mesh-related complications. In a small number of patients, repeat surgery may not resolve complications. • Ask their surgeons about all POP treatment options, including surgical repair with or without mesh and non-surgical options, and understand why their surgeons may be recommending treatment of POP with mesh. After surgery: - Continue with annual and other routine check-ups and follow-up care. Patients do not need to take action if they are satisfied with their surgery and are not having complications or symptoms. - Notify their health care providers if they develop complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that last after the last follow-up appointment.

			- Let their health care providers know if they have surgical mesh, especially if planning to have another related surgery or other medical procedures. - Talk to their health care providers about any questions or concerns. - Ask their surgeons at their next routine check-up if they received mesh for their POP surgery if they do not know if mesh was used. Recommendations for Healthcare Providers: • Recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications. • Choose mesh surgery only after weighing the risks and benefits of surgery with mesh versus all surgical and non-surgical alternatives. • Consider these factors before placing surgical mesh: - Surgical mesh is a permanent implant that may make future surgical repair more challenging. - A mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. - Removal of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain. - Mesh placed abdominally for POP repair may result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.

			• Inform the patient about the benefits and risks of non-surgical options, non-mesh surgery, surgical mesh placed abdominally and the likely success of these alternatives compared to transvaginal surgery with mesh. • Notify the patient if mesh will be used in her POP surgery and provide the patient with information about the specific product used. • Ensure that the patient understands the postoperative risks and complications of mesh surgery as well as limited long-term outcomes data. • Continue to follow the recommendations provided in the 2008 PHN
FDA	Order[30]	3rd January 2012	FDA ordered postmarket surveillance studies ('522 studies') by manufacturers of urogynaecologic surgical mesh devices to address specific safety and effectiveness concerns related to mini-sling devices for SUI and surgical mesh used for transvaginal repair of POP. This order was based on the FDA's evaluation of the published literature, analysis of adverse events reported to the FDA and feedback from the Obstetrics and Gynecology Devices Panel of the Medical Device Advisory Committee.
NICE	Guideline CG40 is updated to CG171 - Urinary incontinence: The management of urinary	11th September 2013	New recommendations regarding MDT working: Inform any woman wishing to consider surgical treatment for UI about: • the benefits and risks of surgical and non-surgical options • their provisional treatment plan. • Include consideration of the woman's child-bearing wishes in the counselling.

[30] FDA, 522 Postmarket Surveillance Studies Database, available online at: 522 Postmarket Surveillance Studies

	incontinence in women[31]		Offer invasive therapy for OAB and/or SUI symptoms only after an MDT review. When recommending optimal management the MDT should take into account: • the woman's preference • past management • comorbidities • treatment options (including further conservative management such as OAB drug therapy). The MDT for urinary incontinence should include: • a urogynaecologist • a urologist with a sub-specialist interest in female urology • a specialist nurse • a specialist physiotherapist • a colorectal surgeon with a sub-specialist interest in functional bowel problems, for women with coexisting bowel problems • a member of the care of the elderly team and/or occupational therapist, for women with functional impairment. Inform the woman of the outcome of the MDT review if it alters the provisional treatment plan.

[31] NICE, CG171 - Urinary incontinence: The management of urinary incontinence in women, The National Archives, 2013, available online at: https://webarchive.nationalarchives.gov.uk/20171102123957/https://www.nice.org.uk/guidance/cg171/chapter/1-Recommendations

			All MDTs should work within an established regional clinical network to ensure all women are offered the appropriate treatment options and high quality care. New recommendations on surgical approaches to SUI: If conservative management for SUI has failed, offer: • synthetic mid-urethral tape **or** • open colposuspension **or** • autologous rectus fascial sling When offering a synthetic mid-urethral tape procedure, surgeons should: • use procedures and devices for which there is current high quality evidence of efficacy and safety • only use a device that they have been trained to use • use a device manufactured from type 1 macroporous polypropylene tape • consider using a tape coloured for high visibility, for ease of insertion and revision. If women are offered a procedure involving the transobturator approach, make them aware of the lack of long-term outcome data. Refer women to an alternative surgeon if their chosen procedure is not available from the consulting surgeon. Use 'top-down' retropubic tape approach only as part of a clinical trial.

			Offer a follow-up appointment (including vaginal examination to exclude erosion) within 6 months to all women who have had continence surgery.
MHRA	Patient Safety Alert – Improving medical device incident reporting and learning[32]	20th March 2014	Patient Safety Alert – Improving medical device incident reporting and learning Patient Safety Alert regarding the joint efforts of NHS England and the MHRA to simplify and increase reporting, improve data quality, maximise learning and guide practice to minimise harm from medical devices by: - sharing incident data between the MHRA and NHS England, reducing the need for duplicate data entry by frontline staff by developing a new integrated National Learning and Reporting System (NRLS). Separate reporting to the MHRA will then no longer be necessary; - giving new types of feedback from the NRLS and the MHRA to improve learning at local level; - clarifying medical device safety roles and identifying key safety contacts to allow better communication between local and national level; - setting up a National Medical Devices Safety Network as a new forum for discussing potential and recognised safety issues, identifying trends and actions to improve the safe use of medical devices.

[32] MHRA, Patient Safety Alert – Improving medical device incident reporting and learning, Alert number NHS/PSA/D/2014/006, 2014, available online at: https://www.england.nhs.uk/publication/patient-safety-alerts-improving-medical-device-incident-reporting-and-learning/

			Instructions are given to continue reporting separately to the MHRA and the NRLS until the integrated reporting system becomes operational.
Health Canada	Safety Information issued to Hospitals – update on 2010 notice[33]	13th May 2014	Recommendations for surgical mesh for POP procedures: • Transvaginal mesh procedures for the treatment of POP are evolving procedures that may carry higher risk of complications than established traditional abdominally-placed mesh or native tissue repair procedures. In many cases, POP may be treated successfully without the use of mesh. • Be aware of the complications associated with transvaginal implantation of surgical mesh for the treatment of POP. Some of these complications may require additional surgery which may not fully correct them. • Surgeons performing transvaginal mesh procedures should have adequate training specific to the devices used at your institution, be familiar with the labelling of each device, in particular, sections concerning warnings and implantation technique. Recommendations for surgical mesh for SUI procedures: The traditional mid-urethral sling procedures for the treatment of SUI have been extensively studied, and are commonly performed for SUI repair.

[33] Health Canada, Recalls and safety alerts, 2014, Surgical Mesh – Complications Associated with Transvaginal Implantation for the Treatment of Stress Urinary Incontinence and Pelvic organ Prolapse – Notice to Hospitals, viewed 9 August 2019, available at: http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/39475a-eng.php

			• Single-incision mini sling procedures are novel techniques for the treatment of SUI and may carry higher risk of complications than the traditional mid-urethral sling procedures. • Be aware of the complications associated with transvaginal implantation of surgical mesh slings for the treatment of SUI. Some of these complications may require additional surgery which may not fully correct them. • Surgeons performing transvaginal mesh sling procedures should have adequate training specific to the devices used at your institution, be familiar with the labelling of each device, in particular, sections concerning warnings and implantation technique.
TGA	Mesh Implant Review[34]	28th May 2014	The overall quality of the literature was found to be poor. As a consequence, there was an absence of evidence to support the overall effectiveness of surgical meshes as a class of products. However, the literature did identify the known adverse outcomes associated with their use. Specifically, the review found that the use of urogynaecological surgical mesh devices for the surgical treatment of SUI and abdominal POP repair was adequately supported by the evidence. Due to the poor quality of the studies undertaken, the evidence to support the use of meshes for transvaginal POP repair, particularly, posterior repair, is not well established.

[34] TGA, Australian Government Department of Health, 2014, Results of review into urogynaecological surgical mesh implants, available online at: Review into urogynaecological surgical mesh implants | Therapeutic Goods Administration (TGA)

			The TGA received 32 adverse events reports involving urogynaecological surgical meshes. The most frequently reported adverse events were pain and erosion. Underreporting of adverse events was recognised. Inadequate training/experience for implanting surgeons was identified as a factor in increasing the risk of complications. Certain patients, including those who smoked or were obese, were found to be at higher risk of adverse events and repeated procedures.
Scottish Cabinet Secretary for Health and Wellbeing	Announcement [35]	17th June 2014	The former Cabinet Secretary for Health and Wellbeing, Alex Neil MSP, announced the Transvaginal mesh implants independent review. The acting Chief Medical Officer, Dr Aileen Keel, wrote to all Health Boards requesting that they consider suspending use of synthetic mesh for these procedures until the independent review reported its findings
CMO/MHRA	Request	2014	CMO asked MHRA to review evidence on risk benefit of mesh implants
NICE	Update to guidance CG171 [36]	November 2015	Deleted recommendation 1.1.14 (regarding referral) of CG171 and replaced it with a link to updated guidance in suspected cancer: recognition and referral (NICE guideline NG12).

[35] Scottish Government, Department of Health and Social Care, 2017, Transvaginal mesh implants independent review: final report, Chapter 1, available online at: https://www.gov.scot/publications/scottish-independent-review-use-safety-efficacy-transvaginal-mesh-implants-treatment-9781786528711/pages/3/

[36] NICE, Urinary incontinence in women: management, updated November 2015, available online at: https://webarchive.nationalarchives.gov.uk/20161104213627/https://www.nice.org.uk/guidance/cg171

FDA	Transvaginal mesh for POP - reclassification[37]	4th January 2016	The FDA reclassified surgical mesh for transvaginal repair of pelvic organ prolapse into class III and required submission of premarket approval (PMA) applications, the agency's most stringent device review pathway. The FDA mandated that premarket approval applications be filed by July 5, 2018 for any surgical mesh marketed for transvaginal pelvic organ prolapse repair. As a result of the FDA's actions, all manufacturers stopped marketing surgical mesh intended for transvaginal repair of posterior compartment prolapse (rectocele)
MHRA	MHRA response to the final report of the Mesh Oversight Group[38]	26th July 2017	John Wilkinson, Director of Devices at MHRA, made the following remarks in response to the final report of the Mesh Oversight Group: "We are committed to helping address the serious concerns raised by some patients. We have undertaken work to assess the findings of studies undertaken by the clinical community over many years, as well as considering the feedback from all sources in that time." "What we continue to see is that evidence supports the use of these devices in the UK for treatment of the distressing conditions of incontinence and organ prolapse in appropriate

[37]FDA, 2016, FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks, Available online at: FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks | FDA

[38] Medicines and Healthcare products Regulatory Agency, 2017, MHRA response to the final report of the Mesh Oversight Group, available online at: MHRA response to the final report of the Mesh Oversight Group - GOV.UK

			circumstances. This is supported by the greater proportion of the clinical community and patients." "In common with other medical device regulators worldwide, none of whom have removed these devices from the market, we are not aware of a robust body of evidence which would lead to the conclusion these devices are unsafe if used as intended."
TGA	Removal of products from ARTG[39]	28th November 2017	Removal of transvaginal mesh products whose sole use is the treatment of POP via transvaginal implantation from the Australian Register of Therapeutic Goods (ARTG). Following TGA review of the latest published international studies and an examination of the clinical evidence for each product included in the ARTG and supplied in Australia, the TGA is of the belief that the benefits of using transvaginal mesh products in the treatment of pelvic organ prolapse do not outweigh the risks these products pose to patients. The TGA also considers that there is a lack of adequate scientific evidence before the TGA for it to be satisfied that the risks to patients associated with the use of mesh products as single incision mini-slings for the treatment of stress urinary incontinence are outweighed by their benefits. These products will be removed from the ARTG. The TGA has issued a range of cancellation notices and notices to impose conditions under the *Therapeutic Goods Act 1989* to a number of sponsors in relation to their mesh and sling products.

[39] TGA, Safety information, 17 May 2019, TGA undertakes regulatory actions after review into urogynaecological surgical mesh implants, available online at: https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants%23actions

NICE	Guidance IPG599 Transvaginal mesh repair of anterior or posterior vaginal wall prolapse[40]	December 2017	Recommendations: Current evidence on the safety of transvaginal mesh repair of anterior or posterior vaginal wall prolapse shows there are serious but well-recognised safety concerns. Evidence of long-term efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. All adverse events involving the medical devices (including the mesh) used in this procedure should be reported to the MHRA. Further research should include details of patient selection, long-term outcomes including complications, type of mesh used and method of fixation, and quality of life.
TGA	Additions to IFU[41]	17th January 2018	Consumers and health professionals are advised that as a result of the TGA's 2017 post-market review of urogynaecological mesh implants, the TGA required sponsors to include information about certain adverse events such as severe chronic pain, groin pain and bladder perforation in the device Instructions for Use (IFUs).
Medsafe (NZ)	Regulatory action on surgical mesh	31st January 2018	Announcement on the outcomes of regulatory action on surgical mesh products in New Zealand. In December 2017, Medsafe used the provisions in the Medicines Act 1981 to request safety information from four suppliers of surgical mesh products in New Zealand. All four

[40]NICE, December 2017, Transvaginal mesh repair of anterior or posterior vaginal wall prolapse Interventional procedures guidance [IPG599], available online at: https://webarchive.nationalarchives.gov.uk/20181103152935/https://www.nice.org.uk/guidance/ipg599/chapter/1-Recommendations

[41] TGA, Safety information, 17 January 2018, Update – Stress Urinary Incontinence (SUI) mid-urethral slings, available online at: https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants#actions

	products in New Zealand[42]		companies responded to confirm that all products removed from Australian register are no longer supplied in New Zealand All surgical mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation will no longer be supplied to the market in New Zealand. One product, a single incision mini-sling for the treatment of stress urinary incontinence, is also now no longer supplied in New Zealand. For those products where changes to warnings in the Instructions for Use were required to be made by the TGA, companies have advised Medsafe these changes have either been implemented or will be implemented once the wording has been agreed.
IMMDS Review	Mesh 'pause'[43]	10th July 2018	The Independent Medicines and Medical Devices Safety Review concluded that there must be an immediate pause in the use of surgical mesh for the treatment of stress urinary incontinence (SUI). This did not apply to abdominally inserted mesh for pelvic organ prolapse and mesh used for rectopexy procedures, which are under a 'high vigilance' regime.[44] The conditions of lifting the pause in the use of surgical mesh, which should be met by March 2019, were as follows:

[42] Medsafe – New Zealand Medicines and Medical Devices Safety Authority, Safety Information, 2018, Surgical Mesh Implants – Regulatory action on surgical mesh products, available online at: https://www.medsafe.govt.nz/hot/alerts/UrogynaecologicaSurgicalMeshImplants.asp

[43] IMMDS Review website, 10th July 2018, Independent Review calls for immediate halt of the use of surgical mesh for stress urinary incontinence, available online at: https://immdsreview.org.uk/news.html#mesh_halt

[44] See guidance document Recommendations of the Mesh Pause Clinical Advisory Group to Medical Directors and Surgical Teams available at https://improvement.nhs.uk/documents/5122/MESH_letter_-_Extension_of_pause_on_the_use_of_vaginal_mesh_29_March_2019.pdf

			i. Surgeons should only undertake operations for SUI if they are appropriately trained, and only if they undertake operations regularly; ii. They report every operation to a national database; iii. A register of operations is maintained to ensure every procedure is notified and the woman identified who has undergone the surgery; iv. Reporting of complications via the MHRA is linked to the register; v. Identification and accreditation of specialist centres for SUI mesh procedures, for removal procedures and other aspects of care for those adversely affected by surgical mesh. vi. NICE guidelines on the use of mesh for SUI are published[45]
FDA	Order[46]	13th July 2018	The FDA ordered the manufacturer of the last mesh surgical products on the market for the transvaginal repair of pelvic organ prolapse in the posterior compartment (rectocele) to stop selling and distributing their products. The company withdrew their product from the market.
MHRA	Response to 'pause'[47]	17th July 2018	Statement on the mesh 'pause', accepting the recommendation made by the IMMDS Review.

[45] NICE, April 2019, Urinary incontinence and pelvic organ prolapse in women: management NICE guideline [NG123], available online at: https://www.nice.org.uk/guidance/ng123
[46] FDA, 2019, FDA's Activities: Urogynecologic Surgical Mesh, available online at: FDA's Activities: Urogynecologic Surgical Mesh | FDA
[47] MHRA, 2018, Pause on the use of vaginally inserted surgical mesh for stress urinary incontinence, available online at: Pause on the use of vaginally inserted surgical mesh for stress urinary incontinence. - GOV.UK

			"This pause has been extended to include vaginally inserted surgical mesh for pelvic organ prolapse and will be implemented through a high vigilance programme of restricted practice." "These procedures have not been banned and during this pause, they will continue to be used when there is no viable alternative and after close and comprehensive consultation between patient and clinician. There has not been any new evidence which would prompt regulatory action and the position of MHRA remains the same on these medical devices."
Scottish CMO	Statement on restricted transvaginal mesh use[48]	12th September 2018	Statement made in parliament, by the Scottish Cabinet Secretary for Health and Sport (Jeane Freeman) requesting that the use of transvaginal mesh in the treatment of both SUI and POP is immediately halted in Scotland, until: 1. Publication of revised NICE guidance on treatment of both SUI and POP 2. Introduction of a restricted use protocol to assure all surgical interventions are "carried out only in the most exceptional circumstances and subject to a robust process of approval and fully informed consent" The halt was not extended to other types of mesh —for example, transabdominal and in hernia repair—these would remain under review

[48] Scottish Parliament, 12th September 2018, Debate on Transvaginal Mesh, available online at: Official Report - Parliamentary Business : Scottish Parliament

TGA	EU alignment[49]	27th November 2018	In response to the Expert Review of Medicines and Medical Devices Regulation (MMDR) the TGA attempted to align (wherever possible) the Australian classification of medical devices with the European Union framework. Reclassifying all mesh medical devices from Class IIb to Class III (high risk). The decision to reclassify ahead of Europe was made due to the serious concerns about risks associated with the use of these devices.
NICE	Updated guidelines for Urinary incontinence and pelvic organ prolapse in women: management [NG123] [50]	2nd April 2019	The guidelines describe MDT setups for the organisation of specialist services, data to be collected from patients on surgical complications, as well as follow-up activity in a national registry. Recommendations were made on assessing and managing mesh complications also. For the surgical management of SUI and POP, new recommendations state that clinicians should support informed consent with the NICE PDAs. Women should be advised that these procedures involve a permanent implant and complete removal might be impossible. Women should also be given written information about the implant, including its name, manufacturer, date of insertion, and the implanting surgeon's name and contact details.

[49] TGA, Australian Government, 2018, Reclassification of surgical mesh devices, available online at: https://www.tga.gov.au/publication/reclassification-surgical-mesh-devices?fbclid=IwAR0HBnoh0JXePmNyrRpa6w-8WYCnzep5HqFV5Gx7yn4qziJuPI1MqDzExNw

[50] NICE, 2019, Urinary incontinence and pelvic organ prolapse in women: management, available online at: https://www.nice.org.uk/guidance/ng123

			In cases where non-surgical options have failed, colposuspension, autologous rectus fascial sling and retropubic mid-urethral mesh sling should be offered. If a woman's chosen procedure cannot be performed by a given surgeon, (s)he should refer them to a clinician who can. Mid-urethral mesh sling for SUI: Surgeons should use type 1 macroporous polypropylene mesh and consider using a mesh sling coloured for high visibility, for ease of insertion and revision. Do not offer a transobturator approach unless there are specific clinical circumstances in which the retropubic approach should be avoided. Do not use the 'top-down' retropubic mid-urethral mesh sling approach or single-incision sub-urethral short mesh sling insertion except as part of a clinical trial. Surgery for POP: Lack of long-term evidence on the effectiveness of procedures and possible complications should be discussed. NICE PDAs should be used to discuss benefits and risks. If a synthetic polypropylene mesh is inserted, the details of the procedure and its subsequent short- and long-term outcomes must be collected in a national registry. Clinicians should consider synthetic polypropylene or biological mesh insertion for women with recurrent anterior vaginal wall prolapse only after:

			• regional MDT review and • discussion with the woman about the risks of mesh insertion and if: • apical support is adequate or • an abdominal approach is contraindicated. This was taken by many to mean that the relegation of transvaginal mesh for POP to 'research only' had been reversed. NICE issued a subsequent clarification, see 24th June 2019 entry below. Transvaginal POP mesh remains 'research only' and the recommendations for mesh treatment of anterior prolapse in NG123 were removed. Posterior vaginal repair without mesh should be offered to women with posterior vaginal wall prolapse. Consider concurrent surgery for stress urinary incontinence and pelvic organ prolapse in women with anterior and/or apical prolapse and stress urinary incontinence. Follow-up: Post-operative review at 6 months should be offered, including a vaginal examination and mesh exposure check. Women should also have access to further referral if they have recurrent symptoms or suspected complications. Complications associated with mesh surgery:

			Refer women with a suspected mesh-related complication to a urogynaecologist, urologist or colorectal surgeon for specialist assessment. For women with a confirmed mesh-related complication, refer to a consultant at a regional centre specialising in mesh complication diagnosis/management. Mesh removal to be discussed within an MDT. Discussion with patients should involve the lack of evidence on the benefits of partial/complete removal, as well as risks. Non-surgical options (topical oestrogen cream) to be discussed also. Refer women who have mesh perforating the lower urinary tract, or those considering excision of mesh sling for persistent voiding dysfunction to a centre for mesh complications for further assessment or management. Discuss division of mesh sling with women who have voiding difficulty after mesh sling surgery.
FDA	Order[51]	16th April 2019	The FDA ordered manufacturers of surgical mesh products intended for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing their products immediately. Based on the review of available evidence, the FDA believed that the benefit-risk profile of mesh placed transabdominally to treat POP and mesh used to treat SUI remains favourable.

[51] FDA, 2019, Urogynecologic Surgical Mesh Implants, available online at: https://www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants

TGA	Recall[52]	17th May 2019	A recall was issued by Boston Scientific Corporation Pty Ltd on 2nd May 2019, to remove any remaining stockroom product from the Australian market for: • Pinnacle LITE Pelvic Floor Repair Kit, Posterior • Xenform Soft Tissue Repair Matrix, with the indication for transvaginal placement of POP.
NICE	Recommendation revision[53]	24th June 2019	Recommendations 1.8.21 and 1.8.22 of NG123, regarding synthetic polypropylene or biological mesh insertion for women with recurrent anterior vaginal wall prolapse, were withdrawn. Instead, the reader is directed to NICE interventional procedures guidance 599, which clarifies the relegation of this mesh to 'research only'. "The replacement of the guideline recommendation with a cross-reference to IPG599 is to provide clarity regarding the relation of NG123 and IPG599 and to take account of a material change since publication in the availability of products CE-marked for the indication which was referred to in the guideline recommendations."
Health Canada	Safety Review[54]	26th July 2019	Health Canada's safety review of non-absorbable synthetic surgical mesh for transvaginal POP repair concluded that non-absorbable synthetic transvaginal surgical mesh should no longer be used to treat posterior compartment prolapse, as recent evidence shows that this use is associated with an increased risk of complications compared to alternative treatment options.

[52] TGA, 2019, TGA actions after review into urogynaecological surgical mesh implants: Update – Boston Scientific mesh recall, available online at: TGA actions after review into urogynaecological surgical mesh implants | Therapeutic Goods Administration (TGA)
[53] NICE, 2019, Urinary incontinence and pelvic organ prolapse in women: management, available online at: https://www.nice.org.uk/guidance/ng123
[54] Health Canada, 2019, Status of non-absorbable synthetic surgical mesh for the transvaginal repair of pelvic organ prolapse in Canada, available online at: https://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70563a-eng.php

			For other types of POP repair, the review concluded that non-absorbable synthetic transvaginal surgical mesh should be used only in specific patient groups: women at significant risk of or who have recurring POP, or women who are unable to undergo other surgical treatments. Health Canada's safety review found that compared to other treatment options, transvaginal implantation of non-absorbable synthetic surgical mesh to treat posterior compartment prolapse has greater risk of complications including pain, repeated infections, and erosion. The use of non-absorbable synthetic mesh for the transvaginal repair of anterior (bladder) and/or apical (uterus) prolapse should only be used for patients who have significant risk factors for recurrence of POP or recurrent POP, or for whom alternative surgical treatments are not appropriate. Transvaginal mesh should no longer be used to treat posterior compartment prolapse. For other types of POP repair (apical, bladder, uterus and cystocele) the review concluded that transvaginal surgical mesh should be used only in specific patient groups: women at significant risk of/ that have recurring POP, or women who are unable to undergo other surgical treatments.
NICE	Guideline IPG669	4th March 2020	Based on a rapid review of the published literature on the safety and efficacy of the procedure, NICE made the following recommendations:

	Bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) using mesh for pelvic organ prolapse - Interventional procedures guidance[55]		- Evidence on the safety and efficacy of bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) using mesh for pelvic organ prolapse is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. - Further research should include randomised controlled trials, and report details of patient selection, technique, improvement in the prolapse, procedure-related adverse events and patient-reported outcome measures.

[55] NICE, 2020, Bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) using mesh for pelvic organ prolapse, available online at: https://www.nice.org.uk/guidance/IPG669https://www.nice.org.uk/guidance/IPG669

Summary of mesh reviews and reports from working groups, regulators, independent reviews and professional bodies:

Organisation	Title	Published	Conclusions
York Health Economics Consortium for the MHRA	Summaries of the Safety/Adverse Effects of Vaginal Tapes/Slings/Meshes for Stress Urinary Incontinence and Prolapse – Final Report[56]	22nd November 2012	The report presents summaries of systematic reviews concerning the safety/adverse events of mesh used to treat SUI/POP. The included studies reported on one or more of the following outcomes: pain persisting after six months, mesh exposure, sexual problems or pain following the procedure, procedures to remove the device or organ perforation (for POP only). TVT: - Postoperative pain/discomfort after 6 months: 0.00% (0.0-1.5%) - Deterioration of sexual function at least 6 months postoperatively: 9.3% (3.8-13.5%) - Erosion: 1.1% (0.0-5,8%) - Repeat operation on mesh: 1.6% (0.5-6.0%) TOT inside-out (including TVT-O) - Postoperative pain/discomfort after 6 months: 0.90% (0.6-5.1%)

[56] M. J, C. M, D. Varley, J. Glanville, *Summaries of the Safety/Adverse Effects of Vaginal Tapes/Slings/Meshes for Stress Urinary Incontinence and Prolapse*. (2012). Available online at: http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con205383.pdf

			- Deterioration of sexual function at least 6 months postoperatively: 2.5% (1.9-3.2%) - Erosion: 2.4% (0.0-5.9%) - Repeat operation on mesh: 0.0% (one study – no range) Single incision system (including TVT-SECUR): - Postoperative pain/discomfort after 6 months: 1.1% (0.0-1.9%) - De Novo sexual difficulties: no studies identified that provided evidence on this - Erosion: 0.0% (one study – no range) - Repeat operation on mesh: no studies identified that provided evidence on this Fascial/pubovaginal sling: - Pain/Discomfort: no studies identified - Deterioration of sexual function 6 months postoperatively: no studies identified - Erosion: 0.0% (one study – no range) - Repeat operation on mesh: no studies identified POP: Anterior/Posterior: Non-absorbable synthetic mesh: - Postoperative pain/discomfort after 6 months: 5.5% (one study – no range) - Deterioration of sexual function 6 months postoperatively: 15.3% (12.8-17.7%) - Erosion: 6.5% (0.9-19.6%) - Repeat operation on mesh: 4.8% (0.9-10.9%)

			- Organ damage: 2.1% (0.9-2.8%) Absorbable biological grafts: - Postoperative pain/discomfort after 6 months: 2.7% (0.8-7.5%) - Deterioration of sexual function 6 months postoperatively: no studies identified - Erosion: 1.2% (0.0-21.4%) - Repeat operation on mesh: 3.2% (1.0-5.4%) - Organ damage: 0.0% (one study – no range) Uterine/Vault Prolapse: Non-absorbable synthetic mesh: - Postoperative pain/discomfort after 6 months: 2.0% (1.2-2.3%) - Deterioration of sexual function 6 months postoperatively: 14.5% (one study – no range) - Erosion: 5.5% (0.0-25.6%) - Repeat operation on mesh: 4.0% (0.8-7.1%) - Organ damage: 1.8% (0.0-7.9%)
TGA	Review into urogynaecologic	28th May 2014	Review into urogynaecological surgical mesh implants (based on TGA monitoring of surgical meshes since 2008) publishes outcomes. The review found that the use of urogynaecological surgical mesh devices for the surgical treatment of SUI and abdominal POP repair is adequately supported by the evidence.

	al surgical mesh implants[57]		However, due to the poor quality of the studies undertaken, the evidence to support the use of these meshes for transvaginal POP repair, particularly, posterior repair, is not well established. The TGA review also found that, while adverse events involving these devices are likely under-reported, the reported complication rate remains low. From July 2012 to 3 April 2014, the TGA received 32 adverse events reports involving urogynaecological surgical meshes. The most frequently reported adverse events were pain and erosion. The TGA review identified inadequate training/experience for implanting surgeons as a factor in increasing the risk of complications. Certain patients, including those who smoked or were obese, were found to be at higher risk of adverse events and repeated procedures.
MHRA	Summary of the Evidence of the Benefits and Risks of Vaginal Mesh Implants[58]	28th October 2014	MHRA's position was that, for the majority of women, the use of vaginal mesh implants is safe and effective. However, as with all surgery, there is an element of risk to the individual patient. This conclusion was said to be entirely dependent on compliance with NICE and other sources of guidance, which emphasise the caution that should be exercised prior to surgery being considered. Whilst some women have experienced distressing and severe effects *"the current evidence shows that*

[57] TGA, Australian Government Department of Health, 2014, Results of review into urogynaecological surgical mesh implants, available online at: https://www.tga.gov.au/behind-news/results-review-urogynaecological-surgical-mesh-implants

[58] MHRA, 2014, A summary of the evidence on the benefits and risks of vaginal mesh implants, available online at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/402162/Summary_of_the_evidence_on_the_benefits_and_risks_of_vaginal_mesh_implants.pdf

			when these products are used correctly they can help alleviate the very distressing symptoms of SUI and POP and as such the benefits still outweigh the risks" MHRA was not aware of a robust body of evidence to suggest that these devices are unsafe if used properly as intended and therefore should be removed from the market. Few adverse incident reports received. However, around 2010, MHRA became aware of increasing concerns about severe adverse effects associated with vaginal mesh implantation. The key issues associated with the use of these devices appear to be mainly clinical, including patient selection, surgical technique, informed consent and patients not being fully apprised of the possible adverse effects associated with the surgery. Patient experiences reported to MHRA mainly included pain, erosion and infection. Other complications reported included relapse of the condition and sexual difficulties. MHRA's review of these reports indicated that although they may be related to the surgical procedure of implanting the vaginal mesh implant, there had not been any evidence that the implant itself was inherently unsafe. From 2005 to 2013, MHRA received 291 adverse incident reports related to vaginal mesh implants for SUI and 110 reports on vaginal mesh implants for POP. Sales data were requested from seven manufacturers from 2005 to 2013. MHRA is aware that there are approximately 29 models on the market and approximately 170,433 units were sold in the UK.

			MHRA's view on setting up a registry was that the decision would need to be led by the clinical community. MHRA would want to influence the establishment and design of any registry in order to ensure that the data collected are appropriate for post-market analysis related to the safety of the devices involved. MHRA state that up to one year post-operation, for procedures involving vaginal mesh implants for SUI, continence in the range of 60-90% is achieved, with peri-operative complications (e.g. erosion, retention, voiding dysfunction etc.) in the range of 1-12% depending upon surgical approach. More limited data at 10 years post-operation suggest that continence is still in the range of 56-85%, indicating that significant long-term benefits are achieved in most women undergoing these procedures. The overall benefit outweighs the relatively low rate of complications. MHRA stated that further work needs to be done to characterise long-term safety in relation to different surgical procedures and mesh types. MHRA was not aware of any evidence that safety differs between different manufacturer's devices. MHRA proposed considering the following: - improved reporting of incidents - structured post-market clinical follow-up - registries or the use of unique device identifiers (UDIs) - Patient Reported Outcome Measures (PROM).

Scottish Independent Review	Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women Interim Report[59]	2nd October 2015	Presents a series of conclusions and recommendations, summarised below: - Robust clinical governance is required. To support decision making, management of the patient should take place in the context of MDT assessment, audit and review. The use of a comprehensive information system will underpin this. **It was recommended that the Expert Group should address this with NHS planners, including an assessment of any administrative support required for the clinical teams.** - Evidence of involvement in MDT working, engagement in audit activity and recording and reporting of adverse events should be a part of consultant appraisal and revalidation of medical staff. **It was recommended that the Expert Group should work with Responsible Officers to include this in the appraisal, and that the Scottish Government should consider alternative methods for adverse event capture.** - Informed consent is fundamental. It was noted that additional work was required to extend patient leaflets to include POP procedures and recommended that the SUI leaflet should be reviewed in the light of this work. Adequate time for discussion and reflection during the consent process was set

[59] Health Performance and Delivery Directorate, Department of Health and Social Care, Scottish Government, 2015, Transvaginal mesh implants independent review: interim report, available online at: https://www.gov.scot/publications/scottish-independent-review-use-safety-efficacy-transvaginal-mesh-implants-treatment-stress-urinary-incontinence-pelvic-organ-prolapse-women-interim-report/

			out as a requirement. It was recommended that patients should be provided with information enabling them to report adverse events. - The lack of extended long term follow up and related outcome data in current studies, including information on quality of life and activities of daily living, should be addressed. **The Independent Review recommended that the Expert Group highlight this knowledge gap to funders of health research and the research community. Opportunities for routine audit should be explored.** - Although there is information both in a professionally led database (the BSUG database) and routine NHS information, there are many gaps. **The development of an information system which is universal, robust, clinically sound and focused on fostering good patient outcomes was recommended.** - The Independent Review expressed serious concern that some women who had adverse events found they were not believed. It was recommended that the training and information available to clinical teams should be reviewed. It was also recommended that patient views should be incorporated into MDT working. - Concern at the use of the transobturator approach for routine surgery for SUI using mesh. Concern also expressed at the use of transvaginal mesh in surgery for POP. Individual cases should be considered in the context of MDT

			assessment, including patient views. **Publication of key research reports was awaited. It was recommended that the Expert Group explore further pathways to ensure the techniques chosen take patient and clinical experience, as well as research evidence into account.**
Mesh Working Group	Mesh Working Group – Interim Report[60]	December 2015	The interim report includes evaluation of both the efficacy and adverse incidents and complications associated with mesh used to treat POP/SUI. Recommendations: Clinical Quality: - Use trust appraisal system to ensure surgeons are appropriately trained and current in their practice, adhere to clinical guidance, comply with national data requirements. and report complications. - NICE to produce a Clinical Guideline that describes, holistically, care for women with POP - NICE to review current Clinical Guideline for Urinary Incontinence (CG171) - NICE to review guidance on complications arising from surgery for SUI and POP. - A nurse helpline service for mesh-injured women to be established. - GP awareness of treatment options for SUI and POP to be improved through the introduction of an e-learning package

[60] Mesh Working Group, NHS England, 2015, Mesh Working Group – Interim Report, available online at: https://www.england.nhs.uk/wp-content/uploads/2015/12/mesh-wg-interim-rep.pdf

			Data and information: - Stronger clinical leadership is needed to promote awareness amongst health care professionals undertaking mesh procedures of the importance of returning all the necessary data associated with their activities. Royal Colleges should consider identifying an individual/individuals to provide this leadership. - NHS employee appraisal systems should ensure surgeons adhere to clinical guidance, comply with national data requirements and report complications. - New OPCS codes should be developed to reflect complications which result in mesh removal and the reason for this. - There is disparity between published evidence and experiential evidence from patients on the nature/extent of problems with these devices. A better understanding of the true nature and extent of the complications needs to be established. The following actions are needed to address these issues: • MHRA should continue to raise awareness amongst clinicians about reporting adverse events relating to mesh procedures. Emphasising retrospective reporting. • Patient support groups and MHRA, liaising where appropriate, should work to encourage women to report AEs. • A one-off information gathering exercise on patient outcomes should be conducted. - A cost/benefit analysis of establishing a registry for these procedures should be undertaken.

			Informed Consent: - Consistent information should be given to patients on mesh procedures for treatment of SUI and POP through the use of collaboratively-designed leaflets. - Discussion between clinician and patient to should cover: the procedure; the alternatives; recommendations; and questions/understanding. This should be recorded, and time allowed once the patient has been given the information leaflet, and the opportunity to ask questions before signing a consent form. The consent form to be kept separate from the information leaflet and not to follow a predetermined template. The GMC guidance should be followed when obtaining consent. - RCOG, BSUG and BAUS should recommend the use of these SUI and POP leaflets by all their members, including private sector. - A letter to be written by Medical Director, NHS England to the NHS Trust Development Authority and Monitor to ask them to ensure Trusts are using the leaflets. - The professional bodies should review of the SUI and POP mesh leaflets (carrying their logos) every 2 years through collaboration and coordination with the four UK nations. - BSUG and BAUS will aim to review and update their information leaflets for all SUI and POP procedures. Other significant comments:

			- Women with serious complications will require treatment at a specialist centre by surgeons specifically trained and experienced in dealing with such complications. - NHS England specialised commissioning teams should ensure that their units include surgeons who undertake mesh removal, or that their unit has a network arrangement with units that do. - All women who are contemplating mesh removal should be aware of the associated risks and complications. These should be explained to them by their GP, or by the performing surgeon.
SCHENIHR	Opinion on the safety of surgical meshes used in urogynecological surgery[61]	3rd December 2015	SCENIHR Recommendations: - Ensure that patients are correctly and comprehensively informed on the benefits and risks associated with the use of synthetic non-absorbable meshes. - Establish European implant registries. - Establish scientific studies to assess the long-term (at least 5 years) safety and performance of synthetic non-absorbable meshes. - Encourage further research into novel design and materials, in particular absorbable meshes, and improved technologies for manufacturing meshes, such as electrospinning.

[61] Scientific Committee on Emerging and Newly Identified Health Risks, 2015, *Opinion on the safety of surgical meshes used in urogynecological surgery*, viewed 12 August 2019, available online at: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_049.pdf

			- Encourage further research into the application of regenerative medicine technology, such as the cellular seeding of graft materials. - Adopt evidence-based Pan European Guidelines. - Develop training programmes for surgeons in association with European medical associations. The SCENIHR also recommended, based on scientific evidence: - The implantation of mesh for the treatment of POP via the vaginal route should only be considered in complex cases, in particular after failed primary repair surgery. - Due to increased risks associated with POP repair using transvaginal mesh procedure, this option should only be used when other surgical procedures have already failed or are expected to fail. - Limit the amount of mesh for all procedures where possible. There is a need for further improvement in the composition and design of synthetic meshes, in particular for POP surgery. - Certification system for surgeons should be developed, based on existing international guidelines and established in cooperation with the relevant European Surgical Associations. - Appropriate patient selection and counselling is required. This should be based on the results of further clinical evidence, which should be collected in a systematic fashion.

			Other pertinent points, based on current evidence: - Type 1 (macroporous, monofilament) is considered to be the most appropriate synthetic mesh for insertion via the vaginal route. Type 1 and Type 3 (microporous, multifilament) are the most appropriate synthetic meshes for insertion via the abdominal route. - There is insufficient evidence on the performance, risk and efficiency of meshes of other materials. - The SCENIHR acknowledges the efficacy and use of implanted meshes for SUI in the majority of patients with moderate to severe SUI. It considers that the associated risk is limited, but recognises the absence of long-term data. Most complications associated with mesh insertion are related to the route of insertion. - The SCENIHR acknowledges that vaginally-implanted mesh for POP is associated with increased risks compared to mesh implantation for SUI. Its use should be restricted to patients selected according to established evidence based clinical guidelines. - The factors influencing the surgical outcomes are: • Material properties (biocompatibility, tissue integration, long-term stability, and mechanical performance over time which includes flexibility, elasticity, aging and resistance to deformation) • Product design (e.g. physical characteristics of the mesh, such as pore size) • Overall mesh size

			• Route of implantation • Patient characteristics (e.g. age, obesity, smoking) • Associated procedures (e.g., hysterectomy) • Surgeon experience - The SCENIHR recognises the importance of following established guidelines, the need for adequate training and clinical experience of the surgeon as well as the need to further improve the design of the device, in particular for use in the pelvic floor, which appears to be a more demanding environment than the abdomen (where the non-degradable meshes have a lower complication rate). - The SCENIHR acknowledges the importance of the identification of high-risk patient groups. Age and obesity have been shown to be associated with increased risk of mesh exposure. This should be investigated further.
Scottish Independent Review	Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence	27th March 2017	Presents a series of conclusions and recommendations, summarised below: - Patient-centred care should include patient choice and shared decision making supported by robust clinical governance. To support shared decision making, management of patients must take place in the context of an MDT, supported by a quality assurance framework. The Scottish Government should consider alternative methods for the capture of adverse events to ensure complete notification. - Evidence of involvement in MDT working; engagement in all relevant local/national audit activity; and the mandatory recording and reporting of

	and pelvic organ prolapse in women - Final Report[62]		adverse events, in line with GMC guidance, should be necessary parts of consultant appraisal and statutory revalidation of clinical staff. The Expert Group should work with Medical Directors and Responsible Officers to ensure this is included in the appraisal of all relevant staff. - Additional work is required to ensure that work on informed consent and patient information leaflets is extended to include all appropriate SUI and POP procedures and that the existing SUI leaflet is reviewed in the light of recent developments. Patients should be provided with the information they need to make informed choices, as well as adequate time to discuss and reflect on it. Patients also require appropriate information, which must include device identification, to allow them to report adverse events if these occur. - Current research studies on safety/effectiveness do not provide sufficient evidence on long-term impact of mesh surgery. The lack of long-term follow up and related outcome data, including information on quality of life and activities of daily living, should be addressed. This knowledge gap should be highlighted to the research community and those that fund health research. Opportunities for routine audit should be explored in conjunction with NHS Scotland.

[62] The Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in women, Final Report, March 2017, available online at: http://www.gov.scot/Resource/0051/00515856.pdf

			- The information derived from professionally-led databases and routine NHS activity data could be improved. It is recommended that the Expert Group works with key stakeholders to address information gaps and ensure that available information is used effectively to support safe and effective care. New data codes for mesh surgery and mesh removal/revision are referenced. - The Expert Group should review the training and information available to clinical teams in primary and secondary care and find ways of incorporating patient views in MDT working. The importance of developing pathways for the treatment of complications is emphasised, ensuring involvement of clinicians with the appropriate skills to take forward the personalised and holistic care. - In the case of surgical treatment for SUI, women must be offered all appropriate treatments (mesh and non-mesh) as well as the information to make informed choices. Management of patients must follow agreed care pathways and the importance of MDT assessment is emphasised. When surgery involving synthetic mesh is contemplated, a retropubic approach is recommended. Care pathways, including one for management of complications, should be developed. - In the surgical treatment of POP, current evidence does not indicate additional benefit from the use of transvaginal implants over native tissue repair. Transvaginal mesh procedures must not be offered routinely. The Expert Group

			must develop appropriate pathways to meet clinical needs and also for the management of those suffering complications.
Mesh Oversight Group	Mesh Oversight Group Report[63]	25th July 2017	"Although some published research suggested the risk of complications from surgery using mesh falls within accepted limits, an increasing number of women have reported complications, sometimes many years after their surgery. The shared personal experience from patients told us that complications can, for some, be very severe and life-altering" Progress in implementing Interim Report recommendations: - NHS Improvement has contacted Hospital Trust Responsible Officers to ensure that hospital appraisal systems can ensure that surgeons are appropriately trained and current in practice. - NICE agreed to update the clinical guideline for SUI (CG171) and extend the scope to include POP. - A Scottish trial of a nurse-led helpline showed the number of women using the service was small. The Oversight Group agreed a different approach based on self-identification by trusts as having the right MDTs and experience to provide advice, treatment or onward referral for women with mesh complications (18 trusts at the time of publication). - To improve GP awareness of treatment options for SUI and POP, a learning resource for GPs was commissioned by NHS England.

[63] Mesh Oversight Group, NHS England, 2017, Mesh Oversight Group Report, available online at: https://www.england.nhs.uk/wp-content/uploads/2017/07/mesh-oversight-group-report.pdf

			- To promote awareness of the need to collect/return data on mesh procedures, BSUG, BAUS and RCOG contacted their memberships by various means, with links to reporting tools and mesh safety information webpages. - To allow for more accurate complication rates to be calculated, OPCS codes have been updated to include the type of procedure and implant and the type of secondary surgery carried out, including total and partial removal of mesh. - MHRA activity regarding increasing awareness of the Yellow Card scheme in order to better understand the nature and extent of mesh complications - A one-off information gathering exercise on patient outcomes was deemed by the Oversight Group not to be feasible. - A working group was formed to take forward the recommendation of a cost/benefit analysis of establishing a registry of mesh surgeries. The subgroup was said to be in a position to report on its findings and make recommendations by November 2017. - Two patient information leaflets were produced in collaboration with the Independent Review of Transvaginal Mesh Implants working group for Scotland. BSUG, BAUS and RCOG committed to promoting the use of these leaflets - Specialised Commissioning of services for women with gynaecological problems is referenced, with mention that NHS England Specialised Commissioning Directorate is working with the members of the Specialised Women's Services Clinical Reference Group (CRG4) on the review of the complex gynaecology service specifications. Other pertinent points:

			- The use of vaginal mesh in primary procedures to treat POP is not supported by the current evidence and this should not be offered routinely for the first surgical intervention. - The current NICE clinical guidance on the management of SUI (CG171 updated November 2015) recommends that surgeons should be performing a minimum of 20 sub-urethral sling procedures each year.
NHS Digital	Retrospective Review of Surgery for Urogynaecological Prolapse and Stress Urinary Incontinence using Tape or Mesh: Hospital Episode Statistics (HES), Experimental Statistics, April	17th April 2018	Key Facts: Between April 2008 and March 2017: - 194,107 patients had urogynaecological procedures of which 96,286 were for urogynaecological prolapse and 101,538 were for SUI. - 100,516 patients had a reported tape insertion procedure for SUI. - 1,195 patients had a reported non-tape procedure for SUI - 27,016 patients had a reported mesh insertion procedure for urogynaecological prolapse. - 71,350 patients had a reported a non-mesh procedure for urogynaecological prolapse. Between April 2016 and March 2017: - 7,245 patients had a mesh insertion for SUI, a reduction of 48% from the period April 2008 to March 2009, when 13,990 patients were recorded. - 133 patients had an initial non-mesh procedure for SUI, a reduction of 6% from April 2008 to March 2009, when 141 patients were recorded.

	2008 - March 2017[64]		- 2,680 patients had a mesh insertion for urogynaecological prolapse, a reduction of 13% from April 2008 to March 2009, when 3,073 patients were recorded. - 7,334 patients had a non-mesh procedure for urogynaecological prolapse, a reduction of 12% from April 2008 to March 2009, when 8,338 patients were recorded. - The number of patients with reported urogynaecological procedures, to treat urogynaecological prolapse or SUI, has reduced year on year from; 25,416 patients in the period April 2008 to March 2009 to 17,349 patients in the period April 2016 to March 2017. A reduction of 32%.
Welsh Task and Finish Group	Report of the Welsh Task and Finish Group to Review the Use of Vaginal Synthetic Mesh Tape and Sheets for Stress Urinary Incontinence	4th May 2018	Recommendation 1: - A new pathway should be developed for women's pelvic health and wellbeing. • This would link with other Welsh Government reviews currently ongoing such as faecal incontinence, endometriosis, pain and expanded to include pelvic health more generally in relation to men's health, continence and colorectal issues. • The pathway should also facilitate the promotion of continence and prevention of prolapse by improved education before the first pregnancy and enhanced post-natal pelvic recovery.

[64] NHS Digital, 2018, Retrospective Review of Surgery for Urogynaecological Prolapse and Stress Urinary Incontinence using Tape or Mesh: Hospital Episode Statistics (HES), Experimental Statistics, April 2008 - March 2017 [PAS], available online at: https://digital.nhs.uk/data-and-information/publications/statistical/mesh/apr08-mar17/retrospective-review-of-surgery-for-vaginal-prolapse-and-stress-urinary-incontinence-using-tape-or-mesh-copy

	and Pelvic Organ Prolapse[65]		Recommendation 2: - The Scottish decision making tool should be modified for use in Wales. The BAUS patient information leaflets should be modified for use in Wales, translated into Welsh. A set of FAQs on mesh issues should also be produced for Wales. Recommendation 3: - An enhanced physiotherapy service is required as part of an agreed Pelvic Health and Wellbeing pathway in Wales. Giving patients the best opportunity to avoid invasive procedures that have greater risks to their health and wellbeing. - NICE guidelines are to be observed in the use of vaginally inserted synthetic mesh. - To promote fully informed consent with patient shared decision making in the choice of procedure for SUI. Recommendation 4:

[65] Report of the Welsh Task and Finish Group to Review the Use of Vaginal Synthetic Mesh Tape and Sheets for Stress Urinary Incontinence and Pelvic Organ Prolapse, May 2018, available online at: https://gov.wales/sites/default/files/publications/2019-03/report-of-the-welsh-task-and-finish-group-to-review-the-use-of-vaginal-synthetic-mesh-tape-and-sheets-for-stress-urinary-incontinence-and-pelvic-organ-prolapse.pdf

			- That colorectal surgeons adopt a suitable shared decision tool for use with patients and the Pelvic Floor Society's statement[66] in relation to abdominal mesh as patient/surgeon choice should be complied with. Recommendation 5: - Each health board should develop its own services to address the needs of local women experiencing pain or complications. - The Pelvic Health and Wellbeing Care Pathway to include a preoperative assessment of pelvic pain. - The establishment of additional multi-disciplinary pelvic pain management clinics in Wales would require funding. The most complex cases could be referred to a residential pain management programme. This too would require funding. - There should be investment in one or more fully accredited multi disciplinary specialist centre for mesh removal in Wales. - In South Wales the two subspecialist trained urogynaecologists continue to collaborate closely with the reconstructive urologist to coordinate the diagnosis, registration and management of complex mesh complications. In North Wales, complex mesh complaints should continue to be referred to Manchester.

[66] Mercer-Jones et al., Pelvic Floor Society, Position Statement by The Pelvic Floor Society on behalf of The Association of Coloproctology of Great Britain and Ireland on the use of mesh in ventral mesh rectopexy (VMR), 2017, DOI: 10.1111/codi.13893, Available online at: https://onlinelibrary.wiley.com/doi/pdf/10.1111/codi.13893

			- A care co-ordinator type role should be developed within the Pelvic Health and Wellbeing Pathway for women with mesh associated pain as a first point of contact in preference to a helpline. Recommendation 6: - Ways for GPs to have direct access to specialist advice should be established. A Welsh equivalent of the GP resource produced by the English Oversight group should be replicated. - FAQs for Wales, such as those developed in Northern Ireland and shared with the rest of the UK, may be helpful in raising awareness with the public and staff. Recommendation 7: - There should be improved recording of procedures and implants linked to the patient record. In the short term, improved clinical coding could support the collection of data until a sustainable solution is agreed. In the longer term, a system of scanning and barcoding of all implants linked to the patient record should be introduced with either a Scan4Safety type approach or potentially linked to the proposal for a new All Wales Theatre Management System. - Any system developed should include a facility for clinicians to add 'soft data' such as decision-making tools and questionnaires completed by the patient in consultation with the consultant surgeon. Other pertinent points:

			- Inadequate recording and data capture in this area of work and of the complications or problems that can potentially arise. - Knowledge of the reporting mechanisms available to women through the Yellow Card Scheme was not initially widely promulgated. - The data on Welsh reporting to the MHRA's Yellow Card Scheme provided for the period 2011 to 2017 indicates that there have been relatively few notifications of complications relating to mesh. - The currently available information does not enable the linking of the episodes of care to the individual patients who have received the recorded treatment, some of which might have been undertaken outside the NHS by the private healthcare services or even outside Wales and the UK. Meaningful estimates of complication rates related to mesh procedures would require a retrospective audit of the statistical data linking the PEDW (Patient Episode Database for Wales) data to individual patient records which would record patient outcomes and complications. - There is no specific code that differentiates between procedures that use biological or synthetic mesh and which would record the clinical move to the use of biological instead of synthetic mesh. - Detailed information on the specific procedures is not available as many of the classification codes used over this period did not differentiate between partial or total removal of mesh or tape.

BSUG	National BSUG audit of stress urinary incontinence surgery in England[67]	11th July 2018	National BSUG audit of stress urinary incontinence surgery in England The audit was supported by HQIP and NHS England. This was a national clinical audit looking at the intra- and postoperative complications and outcomes for SUI procedures. Data were collected for all continence procedures performed in 2013 through the BSUG database. 4,993 urinary incontinence procedures were recorded from 177 consultants at 110 centres in England: 94.6% were midurethral slings (MUS); 86.7% were submitted by BSUG members. Postoperative follow-up data were available for 80% of patients: 92.3% were very much better/much better postoperatively, and 96.3% proceeded with no reported complications. There were 3.7% of cases in which a perioperative complication was recorded. Pain persisting >30 days was reported in 1.9% of all patients. Most patients (60%) had no concomitant surgery. When additional procedures were performed, anterior (527) and posterior repair (518) either in isolation or in conjunction with other procedures were the most commonly performed concurrently.

[67] S. Jha, T. Hillard, A. Monga, J. Duckett, National BSUG audit of stress urinary incontinence surgery in England. *Int Urogynecol J*, (2018).

			3.7% of patients had a reported intraoperative complication or a return to theatre in the postoperative period. Reasons included bladder injury, urethral injury, vaginal buttonholing[68], vascular injury, nerve damage or the need for a blood transfusion during hospital stay. Postoperative follow-up data were available for 3983 (80%) patients. Of these, 3676 (92.3%) patients themselves reported they were very much better/much better at their follow-up visit. Pain persisting >30 days was reported in 1.9% of all patients undergoing MUS but similar in retropubic and obturator MUS. Pain was significantly higher in those undergoing an autologous fascial sling (12.5%) compared with MUS (1.9%), although numbers were small (p<0.01). Graft complications were reported in 1.3% (39) of retropubic synthetic tapes, 1.3% (22) of obturator synthetic tapes and 0.8% (1) of single-incision synthetic tapes within the follow-up period. A considerable reduction in the number of synthetic MUS insertions was reported that halved the number of these procedures by 2017 (4781–2410). Whilst bladder-neck injections saw an eightfold increase (86–713), colposuspensions (combined open and laparoscopic) increased fivefold (40– 211) and AFS fourfold (16–61). MUS continue to account for >70% of SUI procedures.

[68] ' A vaginal "buttonhole" tear is a type of perineal injury which involves a tear in the rectal mucosa and an intact anal sphincter..

			Conclusions: SUI has good outcomes in the short term. MUS has been shown to be a safe and effective treatment option, with >90% being very much/much better at postoperative follow-up. Severe complications were rare, but small numbers for operations other than synthetic tapes made comparisons difficult. There was a trend towards more complications in colposuspension and autologous fascial sling. It has been recommended that all continence surgeons in England use the BSUG database, but it is difficult to mandate use through the current commissioning process for healthcare. The reporting of graft complications in particular requires long-term follow-up. Rates reported in this audit, at 1.3%, represent early complications that are likely to be a consequence of poor healing of vaginal mucosa and midline exposure rather than mesh migration into adjacent organs, which may be detected with longer term follow-up. Data presented in this paper suggest good success of MUS synthetic tapes according to the PGI-I scale and a low risk of complications. Major complications were uncommon. Other operations, such as fascial slings and colposuspension, may have higher complication rates, but more data is needed to establish this.

Scottish Government Independent Report	An Investigative Review into the process of establishing, managing and supporting Independent Reviews in Scotland[69]	26th October 2018	In response to criticism of the Scottish mesh review, the government ordered an inquiry into the way the review was conducted. Having reviewed the evidence, the report concluded that the Mesh Review and the process leading up to the publication of its Final Report were characterised by systematic failures. The Mesh Review was ill-conceived, thoughtlessly structured and poorly executed. Negative factors including irreconcilable differences of opinion of Review members, lack of agreement on the interpretation of evidence, unhelpful political and media influences and pressure to complete the report. The investigation also identified a number of problems with how the Mesh review solicited, monitored and reported relevant declarations and conflicts of interests by members of the Review Group. Recommendations: General and support - Appropriate data on the frequency and nature of 'Commissioning Inquiries, Reviews and Panels' is collected, recorded and reported.

[69]Investigative Review, Department of Health and social care, Scottish government, 2018, An Investigative Review into the process of establishing, managing and supporting Independent Reviews in Scotland, available online at: https://www.gov.scot/publications/investigative-review-process-establishing-managing-supporting-independent-reviews-scotland/pages/2/

			- A distinction should be made between those reviews which have been established within a statutory framework and those which have not, informing public understanding. - There would be merit in setting up a dedicated unit to support commissioned reviews. This unit could provide a common knowledge base for both non-statutory and statutory reviews. Establishing a Review - Guidelines should be developed detailing the procedure which is required to establish an independent review. These guidelines should be in a form which can be modified and standardised over time. - A review should agree, at the outset, what it is seeking to establish and the methodology of how this can be achieved. A methodology to evaluate evidence should be understood and agreed by all members of a review. - Consideration should be given to the creation of a dedicated administrative support unit within the Scottish Government. This unit could be utilised for all commissioned reviews. - A budget should be identified at the beginning of any discussion on the commission of a review. - The chair and members should be advised if there is to be remuneration for membership and, if so, agreement should be reached on the terms of any remuneration.

			The Chair - The appointment process to select the chair should be open and transparent. The commissioning party should ensure that the chair possesses skills specific to the nature of the inquiry. The commissioning party should also have a continuing responsibility to ensure that the chair promotes accountability and confidence in the inquiry process. Support and induction, including background materials, should be given prior to undertaking the role. - A system of mentorships should be established and a pool of those who have had experience chairing a Government review be available to draw upon to support a novice chair. - Potential appointees to chair should have no perceived conflict of interest which may raise doubts on impartiality and independence. The chair should be involved in the selection process of potential review members. The process for the selection of members should be as independent of the subject or area under review, as possible. Criteria should exist to determine the composition and balance of review members in relation to the subject matter under review. - The chair should be the first appointment and that members should be either selected by the chair or in consultation or approved by the chair. - The ultimate responsibility for the content of the minutes rests with the chair. Other Review membership - The degree of external control of a review may have to be considered within the – sometimes competing – constraints on time and costs. The process for

			evaluation and selection should be transparent and accountable and if possible, undertaken by someone outwith the area or subject being reviewed. - A process should be established to manage changes to the membership of a review. The process should include matters such as intimation of any resignations and consideration of replacements and quoracy. - An evaluation of the merits of having special interest representation in a review should be guided by the nature and requirements of the review. Alternative approaches should be considered in whether it is more appropriate to have this representation as part of a subgroup with an effective spokesperson to feedback discussion to the core group. - Group members of a review should have equal access to information and points of contact. - Consideration should be given to providing members of a review with appropriate training and induction covering matters such as conduct and responsibilities, as well as matters pertaining to confidentiality, information sharing outwith the group and how to manage enquiries from the media. Title, remit and terms of reference - Where possible, the chair should be involved in the decision of what the title of the review should be. Material or key terms contained in a title should be explicitly defined and agreed by members. - If possible, the chair should be the principal author in the drafting of the remit.

			- The interests and expertise of all members should be considered when drafting and agreeing the remit. The rationale for the remit should be clearly agreed. - Consideration should be given as to who sets the terms of reference. For example, this could be the chair or the commissioning Minister or a combination of both. All members of a review should have the opportunity to contribute to the development of the terms of reference. The Government should consider providing a guide and template to drafting terms of reference. A period should be set aside to consult on the terms of reference (this must be offset against other possible limitations, for example, constraints on time). - There should be a clear and realistic indication of the timeline of a review. This should be included in the terms of reference. The commissioning party should provide oversight and support to the chair to manage and review any lapse in timescale. Independence and impartiality - The chair should identify areas that may have the potential to compromise the independence of the investigation. This is part of their overall duty to ensure an effective inquiry process and public confidence in the outcomes and recommendations. - A test of 'impartiality' should be applied. This would allow someone with prior knowledge/involvement in the subject matter to be a potential member on the basis that their involvement was disclosed and evaluated. A process should be in place to identify and measure potential conflicts of interest to ensure that a

			proportionate response can be made. The chair has responsibility to lead discussion to consider possible conflicts of interest within the team. The importance of transparency and accountability in the completion of Declaration of Interest should be explained as part of a general induction process. Publication of a report - It should be clearly defined who has editorial control for the structure and composition of any report. There should be a clear understanding of who has responsibility for the printing and publication of any report. - There should be a template that standardises what is presented at the conclusion of a Review, and how this information is presented. Media considerations - If there is reason to believe that the subject under review will attract media and wider public interest, there should be support and media training for both the chair and members of the review. Reassurances should be given to members that advice and support to manage media scrutiny is available.
BSUG	Stress urinary incontinence	October 2018	First national report from the audit and database committee on SUI surgery in the UK from 2008-2017. From 2008 to 2017, 116,037 procedures for urinary incontinence and prolapse were entered onto the BSUG database. There were 145 centres which entered data

	surgery in the UK 2008-2017[70]		and these included teaching hospitals, district general hospitals and private hospitals. The five most commonly performed operations for SUI were included and their outcomes analysed in detail: • Retropubic mid-urethral tape (RP MUT) • Transobturator mid-urethral tape (TO MUT) • Bladder neck injection (BNI) • Colposuspension (open and laparoscopic) • Autologous rectus fascial sling From 2008 to 2017, there were 39,961 RP MUT, TO MUT, BNI, colposuspensions and autologous fascial sling operations for SUI entered onto the BSUG database. It is approximated that the database captured approximately 40% of continence procedures between 2008-2017. 26,765 RP MUT procedures were performed in this period and 9,411 TO MUT procedures were performed. 2,621 BNI, 921 colposuspensions and 252 autologous sling procedures were performed.

[70] BSUG audit and database committee, 2018, Stress urinary incontinence surgery in the UK 2008-2017, available online at: https://bsug.org.uk/budcms/includes/kcfinder/upload/files/BSUG%20National%20Report%20-%20Stress%20%20Incontinence%20Surgery%20in%20the%20UK%20(2008-2017).pdf

			The respective rates of patient reporting via global impression of improvement (GII) as 'Much better' or 'Very much better' was: 90.3% for RP MUT, 91.0% for TO MUT, 54.9% for BNI, 88.5% for colposuspension and 85.7% for autologous fascial sling. Total complication rates (intraoperative and postoperative for the procedures were 15.0% for RP MUT, 8.5% for TO MUT, 2.2% for BNI, 22.4% for colposuspension and 29.5% for autologous fascial sling. A conscious decision was taken to not interpret or comment on the results apart from where an explanation is necessary. Therefor conclusions were not drawn.

Summary of mesh types based on filament structure

Type	Structure	Attributes
Monofilament	Monofilament mesh contains a single fibre	Allows for the passage of macrophages, fibroblast colonisation, collagen production and angiogenesis (growth of blood vessels). The inflammatory response is stopped quickly by allowing the mesh to be incorporated by fibrous tissue, preventing the granuloma formation[71].

[71] Mancuso, E, Downey, C, Doxford-Hook, E, Bryant, MG, Culmer, P. The use of polymeric meshes for pelvic organ prolapse: Current concepts, challenges, and future perspectives. *J Biomed Mater Res*. 2020; 108B: 771– 789. https://doi.org/10.1002/jbm.b.34432

		Monofilament meshes are stiffer than multifilament meshes, with reduced pliability[72].
Multifilament	Multifilament mesh contains multiple fibres that are knitted or interwoven. These fibres contain interstices (gaps between the filaments) of approximately 10 µm[72].	The interstices of 10 µm or less allow bacteria to enter and proliferate[73], but prevent the host immune cells to pass through, thus increasing the risk of infection within the mesh[74]. Multifilament mesh is thought to produce more fibrosis and acute inflammation than monofilament mesh. This is believed to arise from the increased surface area of ~1.57 relative to monofilament fibres[75]. Multifilament meshes are softer and more pliable than their monofilament counterparts[72].

[72] K. Baylón *et al.*, Past, Present and Future of Surgical Meshes: A Review. *Membranes (Basel)* **7**, 47 (2017).
[73] U. Klinge *et al.*, Do multifilament alloplastic meshes increase the infection rate? Analysis of the polymeric surface, the bacteria adherence, and the in vivo consequences in a rat model. *Journal of biomedical materials research* **63**, 765-771 (2002).
[74] S. Kalaba *et al.*, Design Strategies and Applications of Biomaterials and Devices for Hernia Repair. *Bioact Mater* **1**, 2-17 (2016).
[75] M. Binnebösel *et al.*, Biocompatibility of prosthetic meshes in abdominal surgery. *Seminars in Immunopathology* **33**, 235-243 (2011).

Summary of mesh types based on pore size

Type	Pore size[76]	Attributes[76]
I	Completely macroporous: all pore sizes greater than 75 µm. Monofilament	Pores around 75 µm allow ingrowth of fibroblasts, blood vessels, and collagen fibres, which support the formation of fibrous connections with the surrounding tissue. Larger pores also allow bacteria to enter, however. Larger pores are thought to improve the mechanical integrity of the resulting mesh/tissue architecture through increased strength from improved collagen deposition.
II	Totally microporous: pore size smaller than 10 µm in at least one of the three dimensions. Monofilament	Meshes with interstices below 10 µm allow bacteria to survive within the interstices, whilst preventing the movement of granulocytes and macrophages (immune cells which would normally eliminate the bacteria), resulting in higher infection rates. This gives a higher rate of infection. Smaller pore sizes reduce the risk of mesh adhesion[77], however.

[76] P. K. Amid, Classification of biomaterials and their related complications in abdominal wall hernia surgery. *Hernia* **1**, 15-21 (1997).

[77] 'Mesh adhesion' describes the joining of a mesh implant to a tissue or organ, resulting from the formation of scar tissue within and around the mesh implant.

		Smaller pores are thought to produce mesh with high flexural rigidity[78] and reduced compliance[79] (meaning that the mesh is less flexible and more pliable). Type II mesh is also thought to have reduced elasticity compared to Type I.
III	Mostly macroporous with multifilamentous or microporous components	The large pores and small interstices allow bacteria to infiltrate but not macrophages; infection spread and restricted elasticity can be a problem associated to their use.
IV	Submicron pores	Often used for adhesion prevention in abdominal surgery, less in pelvic reconstructive surgery.

[78] 'flexural rigidity', in mechanical science, refers to the stiffness of, or resistance offered by, a material when bending.
[79] 'compliance', in mechanical science, refers to the inverse of stiffness.