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

“Our lives begin to end the day we become silent about things that matter”– Dr Martin Luther King, Jr.

Executive Summary

In October 2017, the Cabinet Secretary for Health and Social Services in Wales asked for a Welsh Task and Finish Group to review the use of synthetic tape and mesh sheets for stress urinary incontinence and pelvic organ prolapse. Clinical leads and academics from the area of uro-gynaecology, colorectal surgery, primary care, physiotherapy, continence and pain management along with representatives from the private health care sector in Wales were gathered to undertake the review, chaired by Professor Simon Emery, Uro-gynaecologist at Abertawe Bro Morgannwg University Health Board. The views of affected patients were sought and carefully considered, although none chose to join the group.

During October 2017 to January 2018, the group looked at the available research and Welsh data evidence, considered the experiences of Welsh women and undertook an examination of the current care pathway for patients experiencing stress urinary incontinence and pelvic organ prolapse. The group also took into account the views of medical device regulators both in the UK and around the world.

The Task and Finish group is pleased to present this report and its associated recommendations, demonstrating a commitment to improving health and wellbeing of the population of Wales and the quality and safety of the healthcare provided.

The recommendations within the report seek to introduce an innovative new pathway for the care of patients with stress urinary incontinence and pelvic organ prolapse in Wales. This incorporates the principles of increased promotion of specialist services for continence, physiotherapy and chronic pain as a preventative, out of hospital care approach for incontinence and prolapse, with surgery as a last resort. This could be part of a new ’pelvic health and wellbeing’ pathway. Also, the group believes that proposed improvements to patient information for patients in Wales will lead to better decision making and a more robust consent process.

The group further recognised the need for improvements to data capture of procedures performed, devices used, complications reported and access to specialist support for patients in the event that they experience problems or have concerns. The report includes some short term clinical coding initiatives and an opportunity to ensure all professionals have knowledge of services available that could quickly improve this situation whilst a longer term solution is pursued.

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CHAPTER 1: WHY THIS REVIEW WAS NECESSARY.

Over recent years the voices of women in Wales adversely affected by their experiences of synthetic mesh and tape implants has grown stronger and we are grateful to their courage and perseverance in bringing this difficult and often personal issue to the fore.

1.1 What Women in Wales told us.

What we were told:

"GP looks at me blank – they have no idea"

Several women have written to the Health Minister in Wales over the last 5 years to raise their concern about mesh and tape implants and outlining their personal experiences. As of December 2017, a total of 25 letters have been received since 2012, either on behalf of or directly from 8 women. One letter was signed by an additional 15 signatures and some Assembly Members (AMs) and Members of Parliament (MPs) have written on behalf of constituents who were not named. The correspondence mostly relates to surgery performed from 2002 onwards within and outside of NHS Wales. Two additional women wrote to the Welsh Government's Chief Medical Officer on this issue, one of which included a composite report of women's experience of mesh, but these may not all relate to patients receiving care in Wales.

What we were told:

"Many Mesh Survivors have developed auto-immune disease brought on by the serious complications of a failed mesh implant. People are dealing with the effects of horrific internal injuries, disability, loss of relationships, they are suffering from infection – some are now resistant to antibiotics, systemic disease and chronic pain on a daily basis"

On the 22 January the Cabinet Secretary met with members of the Welsh Mesh Survivors Group and Jane Hutt AM who shared their experiences of the serious adverse effects they had suffered following the use of synthetic vaginal mesh and tape. They explained their reasons for not wishing to participate directly in the Task and Finish group but provided written evidence and information that they wished to inform the review. The information they provided was shared with the working group in order to fully inform their thinking and forthcoming recommendations. The Task and Finish group asked for the patient experiences,

research documents and media files provided to be summarised and they can be found at **Annex 1.**

Although issues about synthetic mesh used in hernia repair were raised at the meeting with the Cabinet Secretary, it was made clear that this was outside the scope of this review but that the use of mesh in hernia surgery would need to be considered separately.

What we have been told:

"Consultant said he couldn't help and that pain wasn't down to the transvaginal tape (TVT) he had inserted."

Details of the experiences described by women through letters to the Minister and those presented to the Minister on 22 January are set out in **Annex 2** and served to inform the review group. Some of the information presented is general information and is not all necessarily relating to women in Wales.

It must also be said that the Task and Finish group wished to acknowledge that the voices of women who are entirely satisfied with the good outcome of their procedure involving synthetic mesh have not been heard over the course of this review, and indeed these might represent the vast majority. We outline here though the complaints made by women adversely affected by a mesh procedure, to demonstrate how their voice has been heard and included within the group's discussions.

The collective experiences of women adversely affected in Wales suggest that most women have undergone surgery to treat urinary incontinence, vaginal prolapse or birth related injuries resulting in pelvic symptoms.

Women from Wales have described the following adverse experiences following synthetic vaginal tape and mesh operations as outlined below:

- Not being informed correctly of the potential risks involved or the potential side effects and how severe and life changing these could be.
- Not being warned of the potential devastating, life changing complications that could be experienced.
- An inadequate consent process with one patient reporting that 'the only written information provided was the manufacturer's leaflet'.

- Medical staff disregarding a mesh complication as post operative symptoms, and not initially attributing symptoms to mesh and insisting on looking for other causes.
- Being turned away and made to feel like they were ‘making a fuss’, when it later became evident that their symptoms were due to mesh.
- Recounting that ‘consultants can be patronising of their ill and vulnerable patients, often reducing them to tears.’
- Reporting being ‘sent from pillar to post by doctors trying to find out what is wrong.’ And being led to believe this was a rare case with it becoming evident that there are men and women around the world suffering similar or serious side effects.
- Being advised by GPs that the symptoms were ‘normal post operative pain’.
- Inappropriate referrals to other specialists such as orthopaedics, delaying appropriate referrals to a gynaecologist.

Women complained that in relation to reporting of the adverse incidents they were experiencing, they did not feel that surgeons were doing so adequately. They also relate that they were not advised of the ability to self-report these as an adverse reaction to Medicines and Healthcare Products Regulatory Authority (MHRA). Women who later became aware of the facility to report an adverse incident said they did not find ‘navigating the system’ very easy. One woman told us she felt obstructed in making a report by difficulties in obtaining information from both private and NHS hospitals and being told hospital notes were missing. Her experience of trying to pursue her issues with MHRA was that of being ‘bounced around’ departments.

What we were told:

“Told by surgeon that he would use this new stuff that had just come on the market and it would make me feel like Wonder Woman”.

In instances where women reported attempting to make claims in relation to the harm they felt they had suffered and the difficulties they had experienced, they report feeling let down by the legal system, with ‘cases being dragged on until they were out of time’

We heard from women who are concerned about the lack of adequate data on the number of women who are experiencing adverse effects from surgical mesh and that these figures may be greater than those published. They suggest that many cases go unreported because of a lack of knowledge by the patient of the facility to self-report and the fact that reporting by surgeons is not mandatory. They feel there is a lack of statistics to support the safety claims made by the MHRA, the device regulator, and that the number of 'mesh injured women' is higher than the numbers referred to by the MHRA. The Welsh women disagree with the MHRA statistics, who they say continue to insist that 'complications are rare with a side effect rate of 5%' based on inaccurate statistics, low reporting and lack of recognition of side effects'. The women pointed out that some patient information leaflets are not good enough in that they do not give a clear indication of the risks.

To add to their discontent, there is also dissatisfaction with the previous English and Scottish reviews with claims of adversely affected women not being listened to, being side-lined and of a 'whitewashing and cleansing' of the reports produced by these reviews.

Women told us that they worry about the future care of women affected by these issues as some of the long-term effects and risks may not yet be fully known, such as, for example, whether mesh is carcinogenic. They feel more research is required to assess the situation with long term monitoring and trials. Women are distressed by reports in the media and through their 'mesh patient groups' of fellow sufferers who have reportedly died of sepsis or committed suicide.

1.2 What women have asked for:

- To take complaints and concerns seriously by investigating the frequency of side effects to surgical mesh insertions in Wales.
- They insist that all side effects after mesh insertion should be reported to MHRA.
- They insist that surgeons report complications as part of their duty of care.
- That patient information is as accurate as possible.
- Support for women who need redress.
- To actively discourage insertion of surgical mesh.

- To ban the use of surgical mesh.
- To look at MHRAs methods of dealing with adverse complaints and their pursuance of manufacturers (not directing patients to manufacturers when investigations need to be undertaken by impartial bodies not the manufacturers themselves).
- To look at the cost to human life.
- Public warnings like those provided by FDA.
- Surgeons to be fully trained and competent in mesh removal.
- Mandatory reporting of adverse incidents by doctors.
- A fully detailed consent form to be given well before the date of the operation with a full and detailed explanation of the complications of a failed mesh and full disclosure of statistics of failed mesh.
- A victim's register.
- Counselling services for mesh survivors.
- To ban the use of surgical mesh until a full investigative long-term research programme has been completed.
- A Welsh mesh register.
- The procedure to be classified as high risk so that there is mandatory reporting of side effects.
- Better consent and patient information leaflets.
- Justice for mesh injured victims.
- Welsh Government to support a ban in Wales until an accurate long-term evaluation is completed.
- A direction to patients by Consultants and GPs to report to the MHRA any complications or symptoms they feel are related to the mesh insertion whether they be early or late complications.
- Adequate training of GPs to recognise mesh implant rejection and mandatory reporting by GPs to MHRA.
- Long term trials.

These requests are subsequently borne out in a list of bullet points supplied by members of the Welsh Mesh Survivors Group at the meeting with Vaughan Gething,

Cabinet Secretary for Health and Social Services on 22 January as set out on the following page:

In addition to the preceding women's experiences the Task and Finish Group took into consideration the often moving accounts of women constituents recounted by MPs as part of the debate in Westminster Hall on 18 October 2017, the morning of the first meeting of the Welsh Task and Finish Group.

Bullet points supplied by Welsh Mesh Survivors on 22 January at meeting with Vaughan Gething, Cabinet Secretary for Health and Social Services

- ➢ Suspend Mesh use in line with Scotland
  - Ban in New Zealand, many banned in Australia
  - FDA reclassified High risk category certain mesh implants
  - FDA reclassified surgical instruments designed to implant e.g. Trocars
  - EC reclassified or plans to – to high risk
- ➢ Mandatory reporting of Adverse Incidents by Surgeons and a guide to patients to report via the Yellow Card Scheme
- ➢ Register of Mesh Injured People
- ➢ Better training for Removal Surgeons and also training in the use of Native Tissue repairs.
- ➢ Better training for GPs and Consultants to recognise Mesh Complications
- ➢ Wales currently has no Specialist Clinic set up for patients with Mesh Complications. We need expert fully informed medical staff, medical treatment and care. Expert removal Surgeons and specialist equipment – Translabial Scans etc.
- ➢ If there are to be NO specialist Clinics in Wales we need ease of cross-border funding.
- ➢ Better safety measures to be put in place for women and men and can be assessed and audited. Patient Information Leaflets to be fully informative of complications, statistics and advice on the material the mesh is made from e.g. Polypropylene and to make certain that Surgical Tape/Ribbon/Sling Device has the word MESH preceding those terms.
- ➢ Private Hospitals MUST follow these same procedures.
- ➢ Mesh Helpline
- ➢ PIP Assessors to be fully informed about Mesh complications which are invisible and embarrassing.
- ➢ Blue Badge Assessors as above. Possibly help to fill in the on-line forms!!

CHAPTER 2: WHY SYNTHETIC MESH HAS BEEN USED

2.1 Background to the use of Synthetic Mesh in Wales

The synthetic mesh that is currently used for stress urinary incontinence (SUI) and prolapse was developed in Europe around 1995. At the time it was considered a significant improvement over other materials then available. Early studies appeared to indicate that the loosely woven, monofilament, polypropylene fibre used reduced problems of infection or tissue reaction.

Over the next 10 years these light weight tapes became very popular with uro-gynaecologists and patients as they could be inserted easily, with minimal scarring, and as day case operations. The technique appeared to be as effective as the previous standard 'open' operations which were more complicated and had much longer periods of hospital stay and recovery. Many manufacturers copied the original product idea and developed methods of insertion designed to be simpler for surgeons.

Surgeons were doubtful initially about the mesh tapes but were encouraged by studies that appeared to show relatively few complications and a good success rate. Pelvic reconstruction surgeons began to consider how these new meshes could be used to solve the more difficult problem of repairing vaginal pelvic organ prolapse (POP). The techniques then being used had a poor long-term success rate, and often needed to be repeated and were associated with significant vaginal scarring that could result in painful intercourse. Teams in France pioneered the use of broad sheets of the new mesh and developed specialised techniques to support the bladder, bowel and uterus. This was complicated surgery and initial results appeared to be favourable.

2.2 Actions taken when problems were raised

Complications with these new types of device and techniques gradually appeared over time, which are now thought to be caused by the new methods used for fitting the implants and the way these broader sheets appeared to shrink and tighten more than the thinner tapes.

In 2012, the MHRA commissioned York University to review the published literature on the most frequently reported adverse events in light of concerns expressed by patient groups about tension-free vaginal tapes (TVT) and mesh procedures. Whilst their report[1] concluded that the rates of adverse events were generally low, the report concluded that these findings were not straightforward. The report noted adverse event rates associated with surgical techniques using tension-free vaginal tapes for SUI. They were generally in the range of 1–3%; with 9% for deterioration of sexual function for one technique, compared to 2–6 % for surgical techniques using vaginal meshes for POP with a 14-15% rate for deterioration of sexual function.

From around the same time correspondence from Welsh women to the then Health Minister began to raise concerns about the adverse effects they were experiencing following surgery for prolapse and incontinence using vaginal tapes and meshes

By 2013, reports of significant difficulties with the broad synthetic mesh sheets were increasing and many surgeons stopped using them because of the risks involved, in spite of many patients having good results.

This is reflected in the data in Wales, as outlined later in this report that shows that significantly fewer of these broad synthetic mesh sheets appear to have been inserted since 2014.

The thin mesh tapes for SUI continued to be used, as they were thought to be safer. However, as concerns in relation to these have grown over recent times, fewer of these procedures have been undertaken, with more use of physiotherapy services and surgeons encouraging patients to avoid surgery whenever possible. Currently, when surgery is deemed absolutely necessary, alternative methods of surgical support for the bladder using the patient's own body tissue along with traditional methods are increasingly being used.

Concerns about the adverse events associated with the use of vaginal tapes and meshes in surgery were raised in the National Assembly in January 2014. Mark Drakeford AM, the then Health Minister, subsequently provided a written statement

[1] Health Economics Consortium's report: Summaries of the Safety/Adverse Effects of Vaginal Tapes/Slings/Meshes for Stress Urinary Incontinence and Prolapse
http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con205383.pdf

in February 2014 [2] referring to the York University Report; MHRA's opinion on the then known risks and Welsh Government's related guidance to NHS Medical Directors in Wales (January 2013)[3] which had drawn attention to the need for compliance with existing National Institute for Health and Care Excellence (NICE) and professional guidance on the safe and appropriate use of these devices; and directed the use of patient information leaflets jointly produced by MHRA and the British Society for Urological Gynaecology (BSUG) and the British Association of Urological Surgeons (BAUS).

Further to this and consistent with NHS England's advice to clinicians, a Welsh Patient Safety Notice - The Surgical Management of Urinary Incontinence and Pelvic Organ Prolapse [4] was issued in July 2014 emphasising the need to follow NICE guidance; to demonstrate good clinical practice in terms of consent; ensuring that any surgery for insertion or removal of tape or meshes, or repeat surgery was performed in units with relevant specialist expertise; the registration of all procedures on a recognised national database such as those of BSUG and BAUS; the need for regular audits of work undertaken, as well as advocating adverse event reporting to the MHRA.

2.3 Actions outside of Wales

During this period, Wales awaited with interest for the findings of the two national reviews that had commenced - The Scottish Independent Review of the Use, Safety and Efficacy of Trans-vaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women[5] and in England the Mesh Working Group and latterly the Mesh Oversight Group.[6]

Scotland set up its Expert Group in December 2013 to look at ways of improving clinical practice, including the development of pathways of care for women experiencing complications from mesh implants and to improve the consent process by ensuring women were better informed of the risks and benefits of all procedures

[2] Health Minister's Written Statement of February 2014

[3] Senior Medical Officer's letter to Medical Directors January 2013

[4] Welsh Patient Safety Notice (The Surgical Management of Urinary Incontinence and Pelvic Organ Prolapse) (July 2014)

[5] Scottish Independent Review of the Use, Safety and Efficacy of Trans-vaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women

[6] Mesh Working Group and the Mesh Oversight Group in England

available to treat their conditions. The Scottish Expert Group examined the problems in Scotland and following an interim report in October 2015 published their final report in March 2017.

NHS England with the support of the Department of Health and MHRA subsequently set up a separate working group in 2014 to address concerns over the use of mesh devices in the pelvic region to treat stress urinary incontinence and pelvic organ prolapse. This group included UK wide representation. NHS England's intention was not to duplicate the work in Scotland but to build on the work already undertaken.

The NHS England group identified three overlapping priority areas and established three working groups to address these. They were:

- Informed consent working group: to ensure that patients were fully informed about both the beneficial and potentially harmful consequences of surgery through the provision of high quality standardised information and a more consistent consent process;
- Data and information working group: to review the quality of data and information to support decision making by patients and clinicians, including improving the reporting of adverse incidents and procedure coding so that a more complete picture of the level and seriousness of complications could be established; and
- Clinical quality working group: to review the clinical quality of care including improvements to surgical practice and training, clinical guidance and standards, awareness rising of post-operative problems for GPs and improving access to clinical expertise for women with post-operative problems.

The Welsh Government was represented on NHS England's main working group and on the sub-groups by Welsh Government officials and NHS Wales' clinicians.

Following the publication of its interim report in December 2015 a Mesh Oversight Group was set up to progress the implementation of the recommendations in England. Although the recommendations also impacted on Wales, the Welsh Government was not invited to attend the Oversight Group. The final NHS England

report was issued in July 2017 and focused on the actions that had been taken to implement the interim report's recommendations in England and any additional implementation requirements to take forward their final recommendations.

Up to that time, no separate review had been undertaken in Wales. It was intended to await the publication of the final English and Scottish reports and to convene a group to assess their findings and proposals and promote a plan for appropriate actions in Wales.

Over this period of time, correspondence to the Health Minister from patients and former patients continued to highlight the experiences of Welsh women in relation to mesh issues. Clinicians in Wales were aware of the developing mesh debate and few vaginal mesh sheets were inserted from 2014 onwards.

It should also be noted that from mid 2014 the Private Healthcare Sector operating within Wales took action to review their practice and issued guidance to their clinicians on the safety and use of TVT for the treatment of pelvic organ prolapse and stress urinary incontinence and potential complications. Based on the then available evidence and guidance from NICE and MHRA, the use of TVTs continued within this sector, but with the importance of the need for informed patient consent being stressed. Steps were also taken to ensure that the information available for patients was clearer on the risks and benefits of surgery as well as advice given to their hospitals to ensure that surgeons undertaking this procedure were technically competent to do so.

CHAPTER 3: THE WORK OF THE WELSH VAGINAL MESH AND TAPE TASK AND FINISH GROUP

Following the publication of the reports of the English and Scottish reviews, the Cabinet Secretary for Health and Social Services asked that a task and finish group be established to review the use of synthetic mesh tape and sheets for pelvic stress urinary incontinence and pelvic organ prolapse in Wales.

The terms of reference of the group were:

- A review of historic and current practice in the NHS and independent healthcare sector in Wales, including what was known regarding associated complications.
- A review of available evidence as found in routinely collected data, research publications, national reports and feedback from patients and public such as through complaints.
- To consider the use and value of guidance already issued to clinicians in Wales as to whether there was a need for new or revised guidance.
- To advise and make recommendations on the future use of tape and mesh in Wales and any associated patient safety and clinical governance considerations and safeguards including:
    - Services needed by women experiencing adverse effects following existing implants, including local and specialist surgical and pain management services.
    - Procedures to establish fully informed consent including the provision of patient information.
    - BAUS/BSUG registration of any procedure involving tape or mesh implants, and guidance for Responsible Officers to ensure clinical governance.
    - Ongoing routine data collection including activity data (PEDW) and other systems such as the Private Hospital Information Network (PHIN), including clinical audit, patient safety incident reporting (including the MHRA's Yellow Card Scheme), complaints and claims.

- Clinical governance structures, including research, around any potential introduction of new or innovative procedures involving the use of tape or mesh.

It is recognised that the Task and Finish Group could not mandate any recommendations for private healthcare but it was hoped that private providers in Wales would take the subsequent recommendations into account.

The group was chaired by Simon Emery, Consultant Uro-gynaecologist at Abertawe Bro Morgannwg University Health Board. Membership of the group consisted of clinicians, academic and healthcare professionals from obstetrics, gynaecology, urology, specialised physiotherapy, incontinence services, pain management, NHS informatics, primary care, private healthcare and Welsh Government officials. The group was intended to meet three times but a fourth meeting was agreed to include advice from colo-rectal surgeons in relation to their use of abdominally inserted mesh.

Although issues relating to mesh inserted for the treatment of hernia was raised as an issue prior to and during the course of the Task and Finish group it was decided that this should remain outside the scope of this review and that a separate analysis of the issues relating to the use of mesh for hernia repair should be undertaken.

3.1 Data Review

Firstly, to understand the use of synthetic mesh and tape in Wales over the last 10 years and to test what the group heard from clinicians anecdotally - that the use of mesh had decreased over recent years; confirmation in the form of data was sought from the Patient Episode Database for Wales (PEDW), managed by the NHS Wales Informatics Service (NWIS). PEDW is the record for all inpatient and day case activity undertaken in NHS Wales and includes diagnostic and operative procedures. A sub-group was set up to gather and analyse the data available.

These following figures have been provided by the NWIS Classification and Terminology service using the OPCS Classification of Interventions and Procedures version 4 codes, held on the Patient Episode Data Base for Wales (PEDW) and include figures for finished consultant episodes (FCE) with end dates in the date

range 1st April 2007 to 31st December 2017. The full methodology is described in **Annex 3.**

Numbers of Patients and Finished Consultant Episodes Containing Vaginal Mesh or Tape procedures 2007/8 to 2017/18

The table below shows the number of patients who have had a vaginal mesh or tape procedure in each financial year and the number of episodes of care in Wales over the last 10 years:

	Mesh Implant		Mesh Removal		Oversewing of Exposed Mesh		Grand Total	
Financial Year	No. Patients	No. Episodes	No. Patients	No. Episodes	No. Patients	No. Episodes	No. Patients	No. Episodes
2007/08	784	799	62	73	2	2	848	874
2008/09	966	980	49	54	4	6	1019	1040
2009/10	926	937	37	46	1	1	964	984
2010/11	770	777	34	42	0	0	804	819
2011/12	696	705	41	47	0	0	737	752
2012/13	704	712	36	42	0	0	740	754
2013/14	629	636	41	46	0	0	670	682
2014/15	498	504	36	39	0	0	534	543
2015/16	417	422	31	31	1	1	449	454
2016/17	327	328	37	45	0	0	364	373
2017/18 (to date)	142	144	22	26	2	2	166	172
Grand Total	6859	6944	426	491	10	12	7295	7447

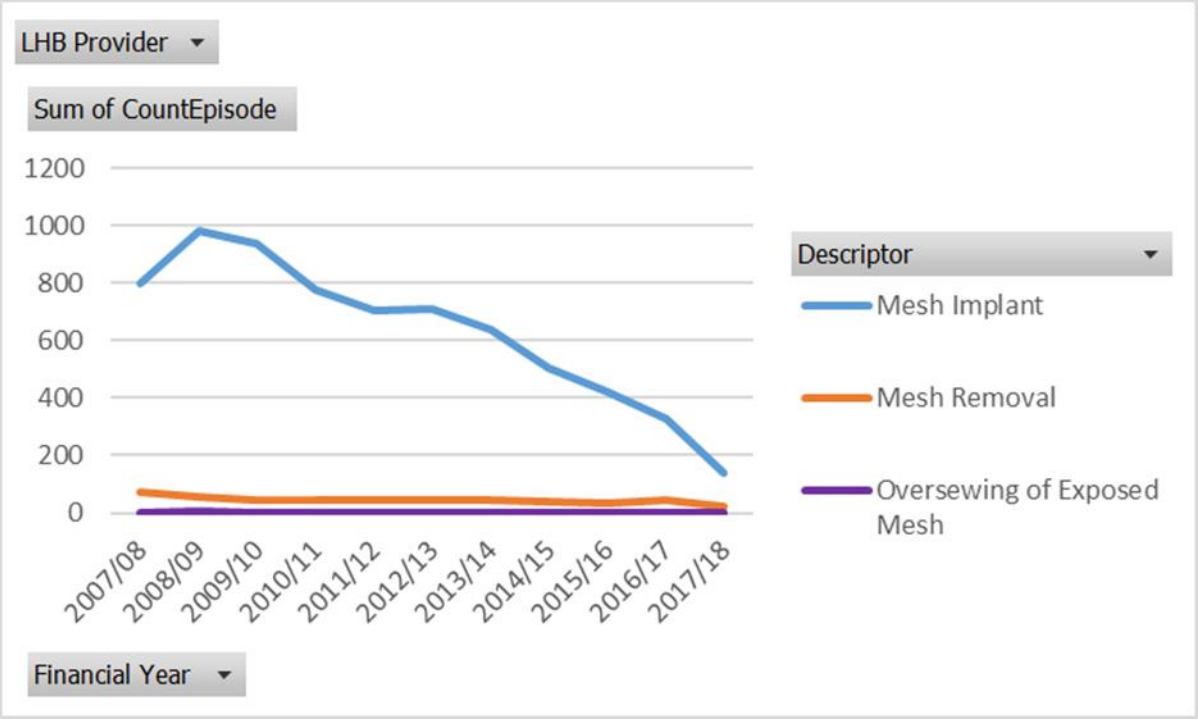
The figures show that over the period 2007 to the end of 2017 there were 6944 finished consultant episodes in which procedures implanting mesh or tape were carried out. During the same timescale there were 503 finished consultant episodes for total or partial mesh or tape removal or over-sewing. Detailed 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.

A total of 6,859 patients received mesh implants and a further 436 had mesh removed or had undergone mesh over-sewing. There are more episodes of care than individual patients as a number of the patients will have received more than one episode of care related to vaginal mesh.

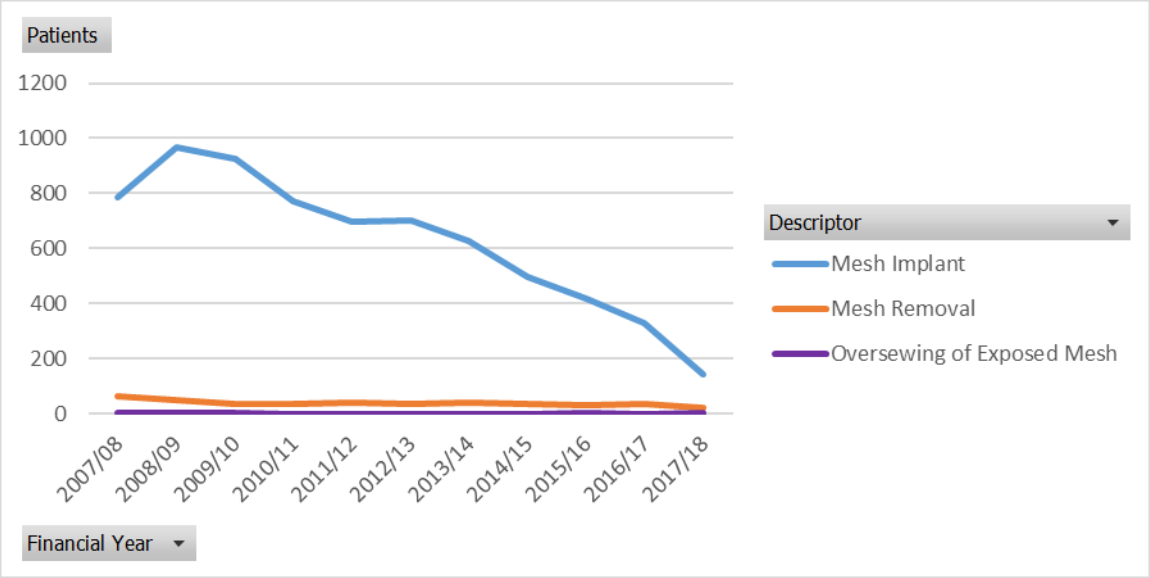
The use of mesh and tape implantation has been on a downward trend over the period investigated, falling from a peak of 980 episodes in 2008-9 to 328 in 2016-17 and 144 over the first 9 months of 2017-18. Episodes of mesh removal have also fallen since 2007-8 but have stayed steady over the last 8 years with an average of

about 40 episodes a year. The over-sewing of exposed mesh has seen very low numbers with a total of 12 episodes over the last decade.

Finished consultant episodes of vaginal mesh or tape procedures:



The number of patients who have undergone vaginal mesh or tape procedures:

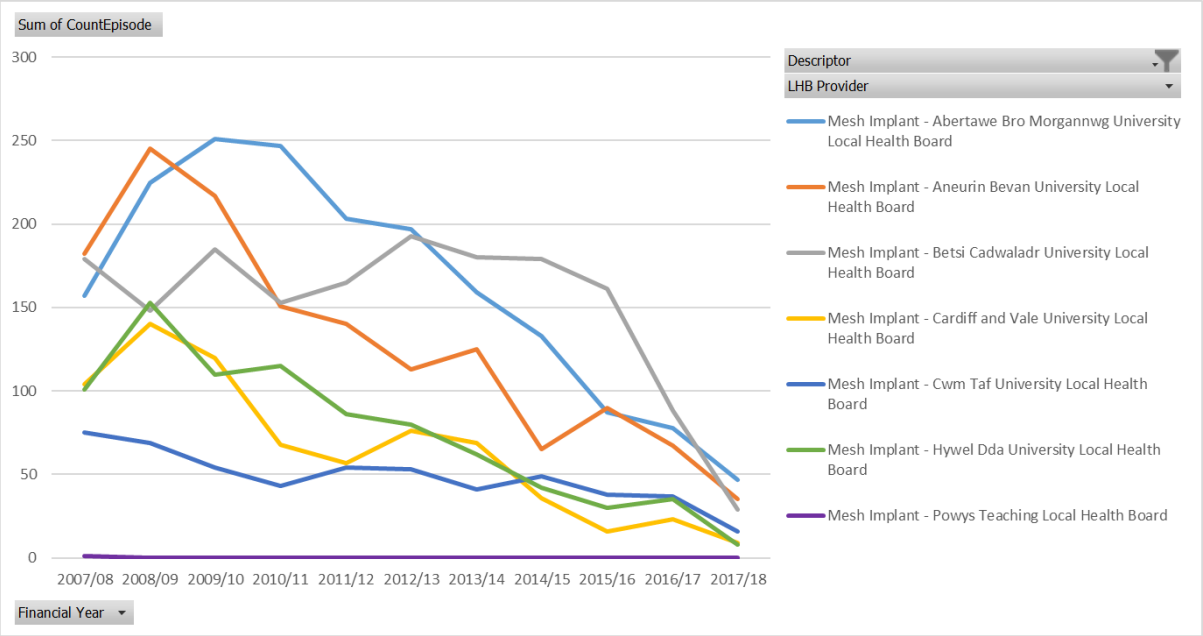


The Table below shows the number of patients in the period 2007/8 to the end of 2017 receiving one or more episodes of care involving mesh procedures. It shows that the majority of patients (92.4%) received one episode of care involving a mesh procedure, a further 443 patients (6.4%) received two episodes and a small number (15 or 0.21%) received four episodes or more of mesh procedures. This implies that 92.35% of patients have not had any complication to date.

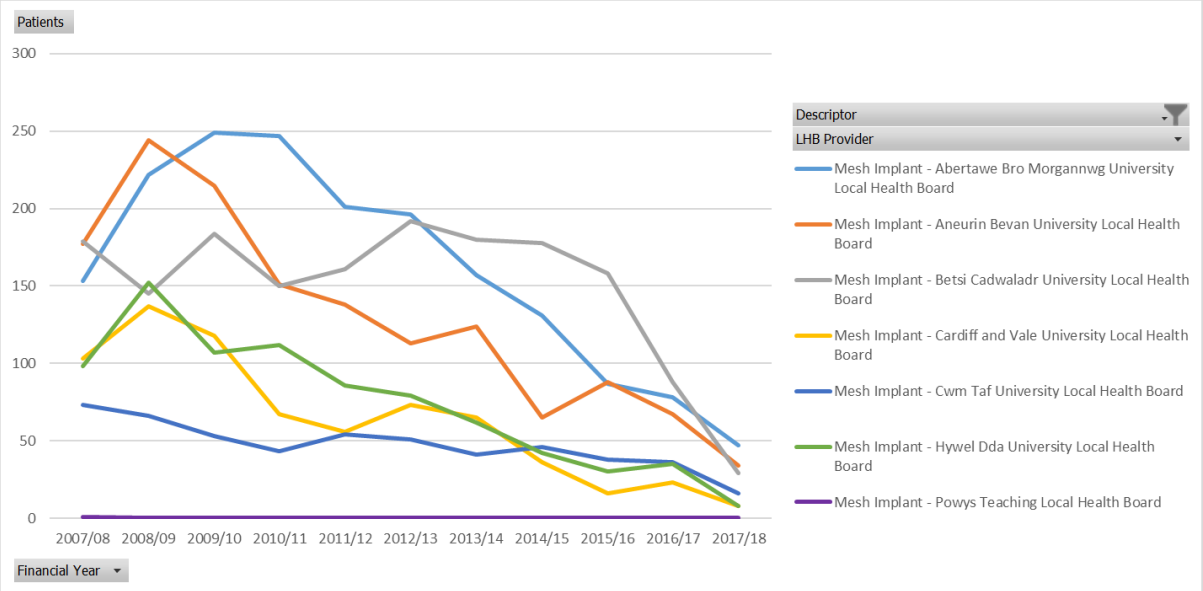
Number of episodes	Number of patients	% of patients
1	6389	92.35%
2	443	6.40%
3	71	1.03%
4	13	0.19%
5	1	0.01%
6	1	0.01%

Looking at the data by University Health Board, in the following tables, the figures show the same pattern over time with the highest level of activity of mesh implantation during the early years followed by a consistently falling trend. In the case of mesh removal some Health Boards exhibit a more erratic declining trend of activity which reflects periodic variations in the smaller number of cases undergoing such treatment.

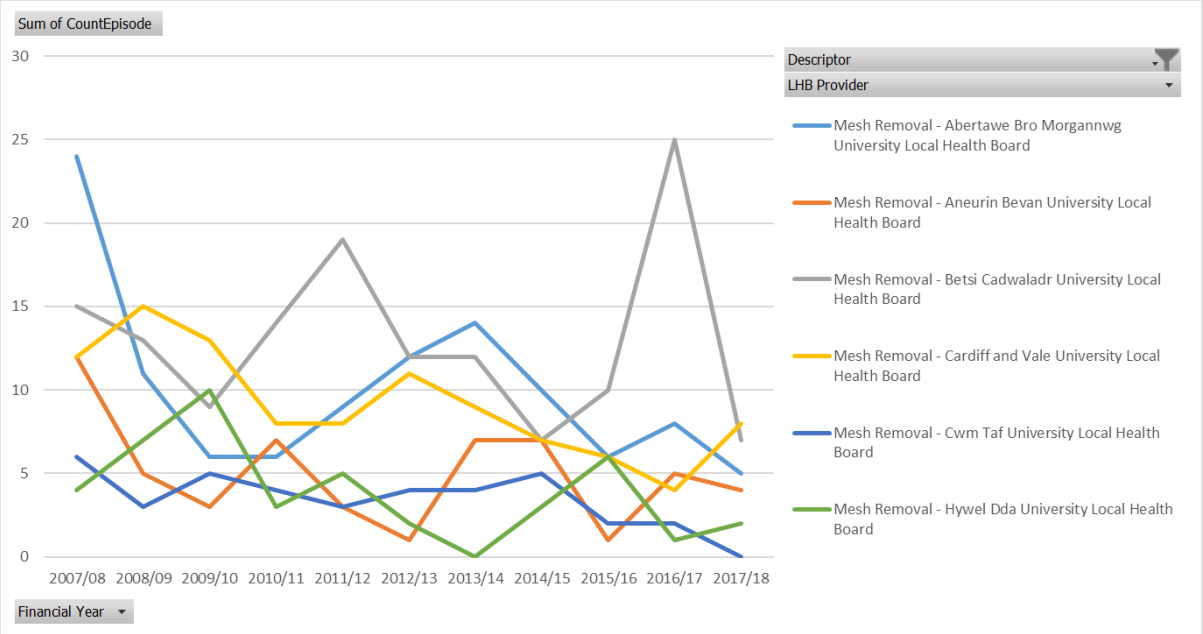
Finished Consultant Episodes with Mesh or Tape Implementation by Health Board:



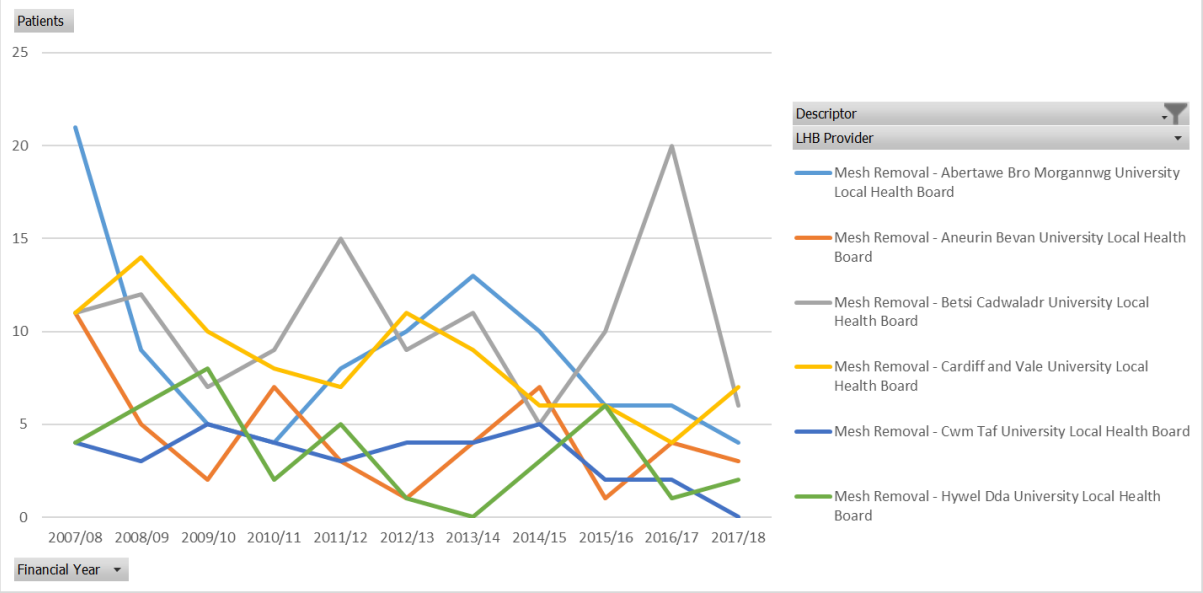
Number of patients having Mesh or Tape Implantations:



Finished Consultant Episodes with Mesh or Tape Removal (partial or total):



Number of patients Having Mesh or Tape Removal:



In addition to the PEDW data above the Task and Finish Group sought information from each of the Medical Directors of Welsh health boards. They confirmed that all but one of the health boards do undertake surgery using synthetic mesh and tape. The exception is Powys which outsources these procedures. All confirmed the trend as shown by the PEDW data that there had been a decline in the use of synthetic mesh and tapes by clinicians in the later years and reported low levels of

complications leading to mesh removal. This is seen as a positive reaction to the advice issued by Welsh Government in 2014. Only three health boards reported receiving any formal complaints related to mesh, resulting in 4 complaints in total. The information received from individual health boards is captured within the Data and Information Repository at **Annex 5.**

3.2 Assessing the number/rate of complications

The assumption has been made that the mesh removal and over-sewing of exposed mesh are an indication of and possible surrogate for the level of complications patients have experienced. Unfortunately, it is difficult to extract accurate data on the number of mesh procedures where complications have occurred as this information is not explicit within the PEDW records. 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. The working group believed that such problems would negate the usefulness of estimating complication rates which have been quoted in a number of other recent studies. Meaningful estimates of complication rates related to mesh procedures would require a retrospective audit of the statistical data linking the PEDW data to individual patient records which would record patient outcomes and complications. Such an analysis would identify the causes of the complications and their relationship to uro-gynaecological and possibly other clinical procedures.

A further issue relating to the accuracy of data, identified by the Task and Finish Group, was that 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. A proposal was discussed to introduce a new standard code in Wales to enable PEDW to monitor these procedures in future. These codes would differentiate between a biological mesh and synthetic mesh and allow a more detailed study of outcomes and complications to be undertaken.

The Task and Finish group sought to gather information from other sources and these were looked at in order to gain a fuller awareness of the potential problems within Wales.

3.2.1 MHRA Yellow Card Information

MHRA monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and those that use them. Adverse incident reports can be made by clinicians or the public through the Yellow Card Scheme which applies to all medicines and medical devices available on the UK market. Wales is reported to have a good record of reporting adverse events relating to medicines to the Yellow Card scheme.

The data on Welsh reporting to the MHRA's Yellow Card Scheme provided for the period 2011 to 2017 (extract at **Annex 4**) indicates that there have been relatively few notifications of complications relating to mesh and mesh-related procedures. Over this period the number of reports relating to mesh used for incontinence in Wales totalled 38, compared to 19 for mesh used for prolapse over the same period with an undisclosed number (<=5) for mesh with an unknown indication.

For the same six-year period, the MHRA received a total of 1,190 incident reports relating to all types of vaginal mesh for the whole of the UK.

The significant increase in the number of reports in 2017 (not whole year figures) in Wales possibly reflects the promotion of the Yellow Card Scheme by MHRA, health boards and patient groups such as Welsh Mesh Survivors. As the yellow card data includes reports from manufacturers, healthcare professionals and the public, the figures may not represent individual patients. In addition, as there is no time limit on reporting, the data may not reflect the dates on which the concerns were identified, which puts a caveat on the use of this data to identify trends.

3.2.2 British Society for Urological Gynaecology (BSUG) and the British Association of Urological Surgeons (BAUS) registers

BSUG and BAUS are professional societies which have developed online database tools aimed to raise the standards of care by clinicians. The database is provided for their members to gather data relating to their subspecialty for the purposes of audit.

The Welsh Government in its Patient Safety Notice (July 2014) to health boards directed that all tape and mesh insertion procedures should be subject to regular

audit and procedures recorded on recognised databases such as those of BSUG and BAUS.

Approaches were made to BSUG and BAUS for details of all procedures relating to mesh and tape implants for Wales over the last three years. To date we have not received a reply. The information collected by these databases is for the whole of the UK and Northern Ireland and is meant for individual clinicians' professional use and it would appear that there is no facility currently available to interrogate the aggregated data to provide a summary and analysis particularly for Wales. The Task and Finish Group were informed by clinical colleagues that not all surgeons in Wales are necessarily members of their respective professional societies and would not have access to these registers to record their data. We understand that BSUG declined a request in 2015 to allow non member clinicians to enter mesh use and complications. Therefore, should it prove possible to extract the Welsh data, it is likely that the data would be incomplete.

3.2.3 Ministerial correspondence

Letters received by Ministers for Health over the last 5 years, whilst being a rich source of information about the experiences of Welsh women, can only provide a limited indication of the scale of the problem.

A total of 25 letters or e-mails had been received either directly from or on behalf of 8 separate women since 2012, up until the establishment of the Task and Finish Group. These small numbers do not detract from the intensively severe personal impact or harm women have experienced as a complication of such procedures.

3.2.4 Limitations of current data capture

The Group's analysis of the information presented above has shown that there is uncertainty about the number of women adversely affected by mesh and tape procedures in Wales. As borne out by both the Scottish and English reviews, there appears to be inadequate recording and data capture in this area of work and of the complications or problems that can potentially arise.

Furthermore, knowledge of the reporting mechanisms available to women through the Yellow Card Scheme was not initially widely promulgated. The issues women

have experienced are often embarrassing and difficult for women to complain about. Those who have reported concerns to the MHRA have reported that they have not found the process easy to negotiate. MHRA figures may also indicate the reluctance of some surgeons to record complications or adverse events.

Whilst clinical coders in every health board are responsible for coding every episode of treatment patients receive by clinical teams from information predominately generated by theatre systems and case note reviews, the data generated by coding can only be as good as the information recorded by clinicians and administrators within these systems and clinical notes.

Each of the information sources reviewed has limitations, which together do not provide a comprehensive view of the number of procedures undertaken or complications arising from them. For example, the PEDW data did not record information on the removal or partial removal of mesh in specific detail up until April 2017 and neither does it easily enable a link to be made between episodes of care and specific patients. The MHRA yellow card information does not enable the identification of patient numbers or specific time periods. Recording by surgeons undertaking mesh and tape procedures on the BSUG and BAUS registers is not mandatory, therefore it is uncertain what proportion of mesh procedures are captured by these databases. Clinicians having to pay to join such societies to enable them to register details of their work could be a disincentive. Finally, the information extracted from the Ministerial correspondence is subjective and provides little comparative information on patients' experiences more generally.

3.3 The Regulatory Environment

The Task and Finish group felt it was important to set out how mesh and similar medical devices are regulated in the UK in order to clarify where responsibility in this area lies and especially as many mesh sufferers have lobbied for an outright ban on the use of synthetic mesh devices.

Mesh implants for use in surgical procedures are regulated as medical devices. This regulation is currently set out in three European Union (EU) Directives that prescribe how devices should be tested before being marketed, sold and used across Europe.

Devices are classified according to guidance set out by the European Commission and the certification process is different for each class of device. This classification system reflects the appropriate conformity assessment routes to be taken to obtain a CE marking.

Under the new EU Medical Device Regulations (EU 2017/745), the classification of mesh implants intended for long term or permanent use will change from a Class IIb device to a Class III device (generally regarded as high risk devices) in 2020. This change reflects concerns relating to these devices and will mean a greater level of scrutiny of the devices in both pre- and post-market assessments. However, many feel the changes are insufficient and not timely to patients' needs.

Once a medical device has been placed in the UK market, vigilance of the safety and effectiveness of the medical device continues after its sale and use in the UK by the MHRA. The manufacturer continues to have a responsibility for monitoring the product and reporting any concerns or serious adverse incidents. Both clinicians and patients can also report concerns about devices through the previously mentioned Yellow Card Scheme. This surveillance is meant to ensure that the device is acceptably safe to use for as long as it is in use.

National Institute for Health and Care Excellence (NICE) also has a role to play in that it sets out to improve outcomes for people using the NHS and other public health and social care services by:

- Producing evidence based guidance and advice for health, public health and social care practitioners.
- Developing quality standards and performance metrics for those providing and commissioning health, public health and social care services.
- Providing a range of information services for commissioners, practitioners and managers across the spectrum of health and social care.

It is therefore important to note that, although patient representatives in Wales have called for a ban on the use of mesh implants, it is not within the power of Welsh Government or the Task and Finish Group to do this. MHRA as the regulator of medical devices in the UK continues to allow the use of these devices on the grounds that from a regulatory perspective the devices comply with the required

regulations and remain acceptably safe when used as intended and recommended by the English and Scottish reviews and existing guidance from the professional bodies. The agency although aware that some women develop complications considers that there are also many women who benefit from the surgical procedures for what can be potentially debilitating conditions.

Action taken by several regulators worldwide, over the course of the Task and Finish Group's review period, was necessarily taken into consideration. These are notably described below:

3.3.1 Recent regulatory decisions

USA regulators

A recently published study examined marketing clearance of vaginal mesh devices through the US Food and Drug Administration (FDA) and concluded that trans-vaginal mesh products for pelvic organ prolapse had been approved on the basis of weak evidence over the last 20 years.

The FDA changed the classification of mesh implants for use in POP procedures to class III devices in 2014 following reports of increased incidents of complications. The FDA ordered mesh manufacturers to address the safety concerns about these products, and to submit new premarket approval applications on all these products to show effectiveness and safety.

Australia

The medicine regulator in Australia, the Therapeutic Goods Administrator[7] (TGA) decided on 28 November 2017 to remove transvaginal mesh products for the treatment of pelvic organ prolapse and single incision mini-slings from use following a review of the latest published international studies and an examination of the clinical evidence. The TGA felt that the benefits of using transvaginal mesh products for the treatment of pelvic organ prolapse did not outweigh the risks to patients. Mid-urethral slings for SUI were not removed at that time but in January 2018 the TGA

[7] TGA actions after review of urogynaecological surgical mesh implants https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants

advised manufacturers that information about adverse events should be included in the device instructions for use.

New Zealand

On 31 January 2018, New Zealand's Medicines and Medical Devices Safety Authority (Medsafe) announced that all products removed from the Australian register would no longer be supplied in New Zealand and the changes to product warnings required by the TGA would be implemented.

NICE

In December 2017 NICE published its interventional procedure guidance: Transvaginal Mesh Repair of Anterior or Posterior Vaginal Wall Prolapse (IPG 599)[8] advising that '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. It noted that evidence of long-term efficacy is inadequate in quality and quantity and 'the procedure should only be used in the context of research'.

The Task and Finish Group welcomed the decision by NICE, having itself reached a similar clinical consensus on how to proceed with these procedures in the future. It considered that the NICE guidance endorsed the view of the group.

In light of the action taken by other regulators of medical devices the Cabinet Secretary for Health and Social Services wrote to MHRA on 23 January 2018 asking that it reviews its position in relation to licensing in the UK. The chair of the MHRA, Professor Sir Michael Rawlins, responded that the devices comply with the regulations and extant guidance , and outlined the agency's on-going work to review activities currently taking place in Europe, their approach to manufacturers for information about their latest clinical evaluation reports, post market data on mesh implants, latest instructions for use and their post market surveillance work to ensure manufacturers' vigilance systems are satisfactory and their oversight of the yellow card system for details of adverse incidents.

[8] Transvaginal Mesh Repair of Anterior or Posterior Vaginal Wall Prolapse (IPG 599) https://www.nice.org.uk/guidance/ipg599

A list of the evidence and research taken into consideration by the Task and Finish Group in reaching its conclusions is set out in a Literature Review Table at **Annex 5**. This is a fast moving topic and the Group endeavored to constantly review evidence as it became available to ensure any guidance and/or advice issued was up-to-date.

Taking all the latest evidence into account, a series of sub-groups were set up to recommend the best treatment, services and information that could be provided to Welsh women as part of the overall care pathway. This detailed consideration enabled the group to determine the specific recommendations within this report and to outline the actions felt necessary to improve services available for women suffering from pelvic organ prolapse or urinary incontinence in the following areas.

3.4.1 Assessment of the Current Care Pathway

Having considering the services currently available to women who suffer from pelvic organ prolapse or urinary incontinence the Task and Finish Group agreed that the best option for women would be to have access to a newly designed care pathway flowing from community based services with, where necessary full access to a multi-disciplinary team of clinicians incorporating continence care, physiotherapy, pain management and when appropriate psychology services. This would ensure consistency of approach across Wales and focus on patient safety and quality. This new 'Pelvic Health and Wellbeing' care pathway, having input from a full range of specialties could offer community based preventive interventions to avoid surgery in the first instance and more clearly identify those small number of patients where surgery would be needed and so potentially reduce the number of high risk surgical procedures carried out in the future. The pathway is illustrated at **Annex 6**.

The individual services identified within the pathway are already available to some extent within each health board area but it is recognized that there will be a need for an assessment of any additional resources that will be required to enhance these services and to enable them to be packaged into a specific patient pathway for this patient group. The implications of this for some health boards could be the need to procure some of the services and roles along with the associated development and training.

For example, the development of a nurse practitioner/care co-ordinator type of role to work with patients to sign-post and facilitate ongoing care could be effective, sustainable and affordable. This would meet some of the requests made by Welsh women and could eliminate the need for a Welsh helpline similar to that run by the Scottish Government.

RECOMMENDATION 1

A new pathway should be developed for women's pelvic health and wellbeing.

a) **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.**

b) **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.**

3.4.2 Patient Information

The task and finish group recognised the ongoing issues through the patient experiences recounted in relation to the availability of appropriate information for patients to ensure fully informed consent for treatments and procedures.

A shared decision tool such as the one developed in Scotland was felt to be a useful starting point for discussion with the patient. The initial patient questionnaire was considered very important in understanding the patient's values. The addition of questionnaires on pain and quality of life at this stage was also considered to be desirable. Once a decision about the course of treatment or a specific procedure was jointly made a further discussion with the patient using procedure specific professional leaflets should ensue.

A sub-group was tasked with looking at the quality of information available for women in relation to the specific procedures to support the consent process. Patient information leaflets from recognised bodies such as BSUG, BAUS, IUGA, EIDO were looked at as well as the Scottish Shared Decision Tool. The latest position in relation to consent in Wales was also taken into account.

The sub-group recommended that the BAUS patient information leaflets were the most comprehensive, easiest to understand, and followed a specific format and style which made comparison with other procedures easier.

Over the course of the task and finish group EIDO (who supply most health boards in Wales with patient information leaflets on a range of procedures) withdrew their patient leaflets for Inserting a Tension-Free Vaginal Tape (OG19), and Inserting a Transobturator Tape (OG32). They reported that due to the rapidly evolving situation in relation to mesh and tapes they could no longer be confident that these were up-to-date and had withdrawn these from their library until the situation was clarified and the range of available treatment options could be presented appropriately and accurately.

In relation to raising general awareness of the issues and informing the public and particularly women who may be affected by mesh and tape complications the Task and Finish Group considered the Frequently Asked Questions (FAQs) document recently produced and kindly shared by Northern Ireland and felt that this provided very useful information for both the public and clinicians.

RECOMMENDATION 2

a) The Scottish decision making tool should be modified for use in Wales.

b) The BAUS patient information leaflets should be modified for use in Wales, translated into Welsh.

c) A set of Frequently Asked Questions on mesh issues should be produced for Wales.

3.4.3 Conservative Treatments and Physiotherapy

The sub group identified to look at the physiotherapy service provision in Wales for Pelvic Organ Prolapse and Urinary Incontinence considered the concerns highlighted by individuals suffering from severe complications as a result of surgical interventions using synthetic mesh and aimed to outline how to improve the future provision of enhanced physiotherapy in Wales based on evidence based guidance.

Initially a literature search was conducted on physiotherapy effectiveness for the management for vaginal prolapse and stress urinary incontinence as set out at **Annex 7**. It was found that the non-invasive and conservative approach of physiotherapy had secured good results in the management of urinary incontinence and vaginal prolapse (Labrie et al 2013[9], Shivkumar et al 2015[10], Hagen & Stark, 2011[11]) and does not have the negative side effects associated with pharmacotherapy (Cannon &Chandler, 2003[12]) or the complication risks associated with surgery (Labrie et al, 2013).

The physiotherapy sub-group further identified that whilst it is positive to see that there is some women's health or pelvic health physiotherapy provided in all health boards across Wales the provision is not standardised across every health board. In addition, the level of provision may not necessarily reflect the population need for that area. The level of expertise and attention to succession planning is also variable across Wales and felt to be of concern. A detailed consideration of the service provision in Wales is provided in **Annex 8.**

RECOMMENDATION 3

a) An enhanced physiotherapy service is required as part of an agreed Pelvic Health and Wellbeing pathway in Wales making it more robust, accessible and sustainable. Giving patients the best opportunity to avoid invasive procedures that have greater risks to their health and wellbeing.

b) NICE guidelines are to be observed in the use of vaginally inserted synthetic mesh.

c) To promote fully informed consent with patient shared decision making in the choice of procedure for Stress Urinary Incontinence.

3.4.4. Colorectal procedures using abdominally inserted mesh

[9] Labrie J, Berghmans LCM, Fischer K, Milani AL, van der Wijk I, Smalbraak DJC, Vollebregt A, Schellart RP, Graziosi GCM, van der Ploeg JM, Brouns JFGM, Tiersma SM, Groenendijk AG, Scholten P, Mol BW, Blokhuis EE, Adriaanse AH, Schram A, Roovers JPWR, Lagro-Janssen ALM & van der Vaart CH (2013) Surgery versus physiotherapy for stress urinary incontinence. The New England Journal of Medicine. 369;12 pp1124-1133

[10] Shivkumar R, Srivastava N, Gupta J (2015) Effects of Bladder Training and Pelvic Floor Muscle Exercise in Urinary Stress Incontinence During Post Partum Period. Indian Journal of Physiotherapy and Occupational Therapy. Vol 9. No 4. Pp194 -198

[11] Hagen S & Stark D (2011) Conservative prevention and management of pelvic organ prolapse in women (Review) The Cochrane Collaboration. John Wiley & Sons Ltd

[12] Cannon TW & Chancellor MB (2003) Pharmacotherapy for Stress Urinary Incontinence. Reviews in Urology. Summer; 5(3): 135–141.

It was agreed to widen the remit of the Task and Finish Group slightly to include the insertion of mesh abdominally as used by colorectal surgeons. A group of colorectal surgeons were invited to an additional meeting in January for a discussion on the way forward on these meshes. They quoted the Pelvic Floor Society's statement in relation to abdominal mesh that evidence suggests that mesh morbidity for ventral mesh rectopexy (VMR) is far lower than that seen in transvaginal procedures and lower than that observed following other abdominopelvic procedures for urogenital prolapse such as. laparoscopic sacrocolpopexy. A copy of the statement can be found at item 54 of Annex 5 Data and Information Repository.

RECOMMENDATION 4

That colorectal surgeons adopt a suitable shared decision tool for use with patients and the Pelvic Floor Society's statement in relation to abdominal mesh as patient/surgeon choice should be complied with.

3.4.5 Support for women predisposed to pain or experiencing mesh complications

Among the most common complaints from women suffering from complications associated with mesh and tape are those of pain and/or erosion.

A literature search considered whether the pain following vaginal mesh surgery was any higher or lower than pain associated with other forms of surgery. The search found that there is evidence to link central sensitisation factors such as fibromyalgia as a predictor of predisposition to post surgical pain. It was considered whether this should be examined further or a recommendation made that this should be included in the preoperative assessment as part of the consenting process.

It was suggested that the number of those affected by pain associated with mesh issues in Wales was likely to be small, although the exact numbers are not known.

There is no specialist provision for pain experienced due to mesh complications. The present situation is that patients would be referred to a mixed condition pain clinic locally.

Currently it would appear that not all patients suffering from mesh complications are however being referred to pain clinics. Where these patients are being followed-up is unclear. Patients experiencing inflammation and pain often opt for the removal of the mesh rather than pain management options. Follow-on procedures such as a division of the mesh or lessening of tension can bring relief. However for patients not wishing to have further surgery or their mesh or tape removed due to the potential reversal of their continence issues a referral for pain management or physiotherapy treatments was considered appropriate.

It was recognised that there was a cohort of patients who could be predisposed to developing heightened sensitivity to pain, a chronic reaction to surgery and/or the mesh material. Where the likelihood of this was identified through pain screening the involvement of a pain clinic early on was considered to be a good strategy.

As part of the care pathway, women should receive pre-screening for pain with specific pain counselling and information preoperatively. This should not just focus on the risk statistics but help women understand fully what type of complications could occur and the impact these could have on their lives. It was considered that information and discussion about potential chronic post-procedure pain and options for managing it should be included in the informed consent for the procedure.

Following the exhaustion of all appropriate conservative treatments, if the joint decision was to proceed with surgery, women should ideally receive conservative pre- and post-operative pain management treatment in order to pre-empt potential problems. Not all patients would require specialist treatment for pain but the involvement of the local pain clinic at an earlier point in the care pathway could increase the success of the treatment.

For women experiencing post-operative pain a multi-disciplinary team approach was favoured rather than management solely by the consultant who inserted the mesh.

In terms of linking this into a pathway, first line services for patients with chronic pain after insertion or removal of tape or mesh could be delivered locally with referral to the local pain clinic. Complex cases, who were not responding to treatments, should be referred to a specialist multi-disciplinary clinic with expertise in pelvic pain management (tertiary service) or a pain management programme. It was recognised

that travel could be difficult for patients with pelvic pain and fatigue. The specialist centre and clinicians could be linked to local clinics to determine the best management pathway for the patient. Referrals could be made at any point in the care and treatment to the specialist multi-disciplinary clinic which could refer patients back to local clinics once the patients' symptoms were stabilised, if further ongoing support was required. For patients with a high level of anxiety aggravating the level of pain experienced the involvement of a psychologist within the multi-disciplinary team (MDT) could be helpful.

It was established that the expertise for the removal of mesh and tape was available in Wales. Further discussion was needed on an appropriate pathway to address the current barriers and difficulties with referrals and whether an MDT or a regional centre was the best configuration. It was felt that a regional centre could be better as this would mean that the required volume of patients to maintain competence and expertise could be attained. It was suggested that an 'open door', flexible approach involving either moving patients to the required expertise at the regional centre or surgeons from the regional centre to the patients was needed.

RECOMMENDATION 5

a) Each health board would need to develop its own services to address the needs of local women experiencing pain or complications.

b) The Pelvic Health and Wellbeing Care Pathway to include a preoperative assessment of pelvic pain.

c) Only one health board in Wales currently has a multi-disciplinary pelvic pain clinic. 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.

d) We recommend that there should be investment in one or more fully accredited multi disciplinary specialist centre for mesh removal identified in Wales.

e) Pending recommendation d) we recommend that:

- in South Wales the two subspecialist trained uro-gynaecologists continue to collaborate closely with the reconstructive urologist to coordinate the diagnosis , registration and management of complex mesh complications utilising the expertise across the region; and

- in North Wales complex mesh complaints unsuitable for local management continue to be referred to Manchester.

f) 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.

3.4.6 Staff training and awareness

It became clear over the course of the review that GPs may not be well informed or aware of the symptoms to look out for in relation to mesh procedures. This was borne out by the evidence provided by the Welsh Mesh Survivors group and by the GP representative on the group. The clinical resources for clinicians produced by the English Oversight group were considered by the Group and in particular the GP representative. This resource in England was thought to be useful in identifying potential symptoms that could arise from mesh implants and the specialist centres to which women with complications could be referred.

RECOMMENDATION 6

a) 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 for Wales with a list of specialist centres or their equivalent.

b) Frequently Asked Questions for Wales, such those as developed in Northern Ireland and kindly shared with the rest of the UK, could be helpful in raising awareness with the public and staff.

3.4.7 Data capture linked to audit

The data sub-group, as well as extracting the information previously set out within this report from the PEDW record, also considered what could be done to improve data capture in Wales in both the short and long term, taking into consideration that both the English and Scottish reviews had recognised the difficulty in obtaining comprehensive and accurate information and were working to address this.

The group was aware of proposals, being taken forward by the Registry Subgroup of the English Mesh Oversight Group to establish a national registry for SUI and

prolapse interventions including tape and mesh procedures, possibly building on the current two voluntary registries held by BSUG and BAUS. Recognising the financial implications of establishing a registry, a cost/benefit analysis has been underway to ascertain whether such a registry would be viable and to scope out the possibility of building on the existing data sources.

The recently approved EU Medical Device Regulations will require that all medical devices placed on the market should be assigned unique device identifiers (UDIs) to allow their unambiguous identification. The UDI is to be recorded using automatic identification and data capture techniques which could include barcodes, smart cards and biometrics. It is envisaged that these arrangements would come into effect by 2020. In addition the new regulations will require public access to the information.

It would be necessary to future proof any registry introduced to be compatible with the new EU regulations and the roll-out of the Department of Health's 'Scan4Safety' project which will introduce the barcoding of devices such as breast implants, replacement hips, medication and surgical tools allowing the traceability of implantable medical devices in all English hospitals by 2021. The 'Scan4Safety' initiative is currently being piloted in 6 English trusts.

A positive benefit demonstrated by Scan4Safety is that of using a common language on ways of working and standards within the wider NHS which will allow for better consistency of data.

There are similar proposals in NHS Wales which entail the development of a new theatre management system for the whole of Wales. This proposal would allow the scanning of medical devices/ implants used in theatres and for these to be automatically entered into patients' records and a national data repository with the ability to be interrogated in order to identify all women who had received specific mesh procedures and devices.

The group considered potential short term solutions within Wales to some of the data issues identified. A worldwide system called SNOMED CT is being rolled out in Wales which will bring a global language for health terminology and clinical coding. This will benefit both patients and healthcare professionals by improving the quality of health records which should facilitate better clinical decisions and analysis,

leading to higher quality, consistency and safety in healthcare delivery. The common information standards associated with this initiative will mean that health and care organisations will have the ability to share and compare data. The rollout of SNOMED CT in primary care in Wales is well advanced and ahead of the rest of the UK. This will be followed by a roll-out within acute hospital care. Whilst the benefits of this system are welcomed the information subgroup also considered what could be done to further improve clinical coding whilst roll-out was awaited. It was identified that as there are currently no Office of Population Census and Surveys (OPCS) codes to identify the type of mesh used within a procedure as to whether it was a synthetic versus a biological mesh. It was proposed that supplementary codes could be developed in Wales to specifically identify the type of implants used. It was suggested that this could be introduced in Wales before the introduction of SNOMED CT. If the codes were agreed these could be issued to Medical Directors with guidance for health board coders and clinicians.

RECOMMENDATION 7

It was agreed that there should be improved recording of procedures and implants linked to the patient record.

To achieve this, 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.

CHAPTER 4: LIST OF RECOMMENDATIONS

RECOMMENDATION 1

A new pathway should be developed for women's pelvic health and wellbeing.

a) 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.

b) 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.

RECOMMENDATION 2

a) The Scottish decision making tool should be modified for use in Wales.

b) The BAUS patient information leaflets should be modified for use in Wales and should be translated into Welsh.

c) A set of Frequently Asked Questions should be produced for Wales.

RECOMMENDATION 3

a) An enhanced physiotherapy service is required as part of an agreed Pelvic Health and Wellbeing pathway in Wales making it more robust, accessible and sustainable. Giving patients the best opportunity to avoid invasive procedures that have greater risks to their health and wellbeing.

b) NICE guidelines are to be observed in the use of vaginally inserted synthetic mesh.

c) To promote fully informed consent with patient shared decision making in the choice of procedure for Stress Urinary Incontinence.

RECOMMENDATION 4

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RECOMMENDATION 5

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b) The Pelvic Health and Wellbeing Care Pathway to include a preoperative assessment of pelvic pain.

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- in North Wales complex mesh complaints unsuitable for local management continue to be referred to Manchester.

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RECOMENDATION 6

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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.

Patient Experiences – Welsh Mesh Survivors' Group

Annex 1

Ref	Document	Date rec	Issue/Op	Country (If known)	Detail/Journey
PE/01	**Patient Experience – Collated - Detailed journey (various)**				
PE/01/01	Collated Patient Experience responses – Wales				UK Mesh survivors experiences of mesh complications (*detailed experiences included within **PE/02** below*)
PE/01/02	Collated Patient Experience responses – England				UK Mesh survivors experiences of mesh complications
PE/02	**Patient Experience – Detailed journey:**				
PE/02/01	Information on patient journey – **(Welsh Mesh Survivor)**		**Pelvic organ prolapse and SUI – Fitted with J&J Ethicon Mecilene Mesh**	Wales	• **Fitted with J&J Ethicon Mecilene Mesh for pelvic organ prolapse in 2002. In addition, an abdominal and vaginal hysterectomy.** • Problems from the start – Bleeding and intense pain, difficultly with emptying bowel and bladder. (Told it was post-op pain). • Had several mesh removal operations. Vaginal operations and open abdominal operations and laparoscopic operations, residual mesh remained. • Suffers with severe osteoarthritis. • Offered a stepped management process: Persistent Colonic irrigation, leading to ACE, leading to the need for a colostomy. • Suffers from sudden onsets of dizziness. • Medication - Flagyl, Paracetamol and prescribed Mefenamic acid, Epsom Salts, Glycerine suppositories and sometimes a low dose of Valium. • **Helped** – Seeing a Pain Management Specialist – Mindfulness and how to take back control of life.

PE/02/02	**Letter** from UNISON	13 November 2017			• Unison supported the campaign to ban the use of Surgical Mesh Implants pending a full investigation and long-term follow up of Mesh implanted patients.
PE/03	**Patient Experience – Detailed journey (various)**				
PE/03/01	**Email** - Information on patient journey - ***to*** **Welsh Mesh Survivors**.	**12 October 2017**	**TVT fitted**	Wales	• **<u>TVT fitted in December 2013</u>**. • At the pre-op appointment at the Urologists Clinic risks of the mesh were not outlined. However, was told that alternative surgery would leave pelvic post surgery pain and nothing could be done about it. Surgeon advised mesh. • Following the operation there was discomfort but this was manageable, passed urine ok, no more leaks. • Jan 2014 – mesh eroded the vagina. Went back for further surgery • May 2014 - it happened again. • Jan 2017 – Painful having intercourse. Saw the surgeon whom was not helpful at all.
PE/03/02	**Email** - Information on patient journey – ***to*** **Welsh Mesh Survivors.**	**12 October 2017**	**TVT fitted + Removal**	Wales	• **<u>TVT fitted in December 2011</u>.** • Immediate issues – couldn't move right leg, pain in lower abdomen and back and right groin. Infections in operation sites, 3 lots of antibiotics, saw consultant that confirmed 'mesh exposure of the right arm'. • Admitted Feb – Thought that this was for removal but instead had steroid injections into the subcutaneous tissue. This did not alleviate pain – sent for Physiotherapy which was extremely painful. • Had op to remove TVT in August 2012, pain free for 1 year. Following this, constant pain again, had all scans however all came back clear. • Saw a different consultant who said that only half of the mesh had been removed. • **<u>Aug 2015 – removal</u>**, couldn't pass urine for 3 week having to self catheterise, wound infections and bladder infection. • All then ok for 1 year and all started again. Inflammation inside.

					Spent 6 years in constant pain and discomfort and incontinent. Unable to sleep, constant flare ups.
PE/03/03	**Email** - Information on patient journey – ***to*** **Welsh Mesh Survivors.**	**12 October 2017**	**Gall bladder operation – Led to an incisional <u>hernia and needed mesh</u>.** **+ mesh removal**	Wales Removal – England	• **<u>2000 went to a Welsh Hospital to have a routine key hole Gall bladder operation.</u>** • During the operation the Hartmann's pouch was removed rather than the cystic duct with incomplete occlusion with clips. • Within hours of the operation rushed back into surgery. • **<u>2002 – The cutting during the emergency operation had led to an incisional hernia the size of a melon that needed mesh</u>**. Not told of any complications. • 2003- Mesh had to come out, if it didn't, told would be in a wheelchair at the end of the year and dead the following. • **<u>2004 – England to get the mesh removed. Small part of the bowel had to be removed as the mesh had wrapped around it. A thicker mesh was placed.</u>** • Offered to attend chronic pain clinic however, needed to find own transport – needed to take 2 buses. • Since mesh put in – 15yrs ago – in chronic pain. Being treated by GPs who have no idea about mesh.
PE/03/04	**Email** - Information on patient journey – ***to*** **Welsh Mesh Survivors.**	**12 October 2017**	**Vagina had prolapsed – TVT fitted.**	Wales	• **<u>Vaginal repair in 2008 at a Welsh hospital. Vagina had prolapsed and sling was mentioned and fitted (unable to recall detail of what had been used)</u>** • 2010 had severe pain down legs and groin. Cortisone injections did not help. • 2012 – major surgery on a global prolapse and told that the mesh had moved and would be having TVT tape, nothing further was said. • Lot of pain following surgery, couldn't empty bladder at all. • Currently - unable to empty bowel, significant pain in legs, back, groin and feet, cannot walk some days. • On waiting list to see a gynaecologist.
PE/03/05	**Email** - Information on patient journey – to **Welsh Mesh Survivors.**	**12 October 2017**	**Birth of son was mismanaged – Left with multiple pelvic organ prolapse and SUI.**	Wales	• **<u>Started in 2004 – birth of eldest son - Whole birth was mismanaged.</u>** • **<u>Left with multiple pelvic organ prolapse and SUI.</u>** • First to be addressed was SUI with a TVT. Initially all was fine. Now unable to pee and in a lot of pain.

			Addressed SUI with TVT.		• 2011 – Had a laparoscopic ventral mesh rectopexy but left in a lot of pain – consultant described it as a tug of war between the sacrum and the operation failed so the prolapsed was pulling down on the mesh constantly. • Re-do the rectopexy after much fighting through the IPFR process and a saxcrocolpopexy again with mesh in 2016. • Unable to have intercourse, constant pain, taking 23 pills a day and 33 years of age. • Want to get removal but no removal specialists in Wales therefore going though IPFR process again to see a specialist consultant in England.
PE/03/06	**Email** - Information on patient journey –***to*** **Welsh Mesh Survivors.**	**12 October 2017**	**TVT fitted**	England	• Operation performed in England – now living abroad. • Operation back in 2007, again in 2008 as mesh eroded. Diagnosed with fibro, hair loss, enema, depression, did not cure urine incontinence and currently waiting to be admitted in Malta as mesh has again eroded vaginal wall. None of the side effects explained. Not one surgeon in Malta will remove the mesh.
PE/03/07	**Email** - Information on patient journey – to **Welsh Mesh Survivors.**	**13 October 2017**	**Ethicon Gynaecare TVT fitted to fix incontinence**	Wales	• **Implanted 2014 (46). Problems began few days/week after implant.** • Went to see GP initially due to severe pain – told it was post operative pain caused by stich irritation. • Suffer from anxiety, trust issues and fibromyalgia. • Placed on Pregabalin for the next 3 years to help with pain. – not help. • Undergone further procedures and almost 2 years after insertion a partial mesh removal (2016) and urethroplasty to reconstruct the urthera as the mesh had thinned the vaginal wall. • Remove the remainder of the mesh would cause server nerve damage. • Bladder does not work properly, they could try and fix but would lead to self catheterising.
PE/03/08	**Email** - Information on patient journey – to **Welsh Mesh Survivors.**	**13 October 2017**	**TVT fitted for SUI**	Wales	• **TVT fitted in January 2014 for SUI** • Presented with chronic pain and unable to empty bladder after surgery. • Family life affected. • Even though the compilations were linked to mesh, led to

					believe it was an orthopaedic issue, had not been seen by a gynaecologist for 3 years. • Self catheterise, suffers from depression and anxiety.
PE/03/09	**Email** – Information on patient journey – ***to*** **Welsh Mesh Survivors.**	**13 October 2017**	**Mesh for different hernias**		• **Surgery in 2007. Mesh for hernias** • Never told of any negative outcomes, only possible infection of the wound post surgery. • Ended up staying in hospital for 2.5 months due to infections. • Due to have a hip replacement but due to mesh issue they will no longer operate on hip. • Caused a lot of hernias in the groin, left disfigured. Told will end up with a colostomy because of the mesh.
PE/03/10	**Email** - Information on patient journey – ***on behalf of a friend to*** **Welsh Mesh Survivors**.	**13 October 2017**	**Mesh Implanted to cure incontinence after childbirth.**		• **Mesh Implant 4 years ago to cure incontinence after childbirth.** • Following the operation way of life changed immediately. • Not provided with any information of possible negative effects of mesh (pre op). • Unable to work, relationships with husband suffering, sexual intercourse painful. • Relationship with partner and children suffered. Having to self catheterise which had led to infections and discomfort. • Become depressed and in severe constant pain.
PE/03/11	**Email - Information on patient journey – to *W*elsh Mesh Survivors.**	14 October 2017	**TVT procedure in 2006 for mild SUI**		• **TVT procedure in 2006 for mild SUI.** • Fit and healthy beforehand. • Told by consultant that it was a gold standard procedure with little risks of side effects. • Told that a net was used to support the urethra, procedure would take 30mins and home the same day. • Around 2 years later noticed that the SUI had started to come back, also had first ever UTI and given antibiotics from GP, also started to have severe pain in limbs and neuropathic symptoms. • Referred to GP for MRI and then referred to pain clinic. Prescribed specific medication for neuropathic symptoms. • Now suffers from incontinence and constant overactive bladder symptoms as well as continual UTIs, sexual intercourse very painful. • Currently seeing specialist consultant in England - told issues

					was due to foreign body giant cell reaction. Recommended removal of TVT this would involve 2 operations.
PE/03/12	**Email - Information on patient journey – *to* Welsh Mesh Survivors**	14 October 2017	**2 mesh operations for prolapse, but no incontinence until the last op in 2013. Both operations were private**		• **<u>Had 2 mesh operations for prolapse, but no incontinence until the last op in 2013. Both operations were done privately.</u>** • Suffers from leaking bladder and dull ached in right lower back. • Went back to the hospital – advised of another operation that would correct the incontinence - this only done privately, quickly. • Didn't want another op and wanted to try pelvic floor exercises (herself). • Back pain and incontinence got worse and GP prescribed repeat prescription and painkillers, painful UTI's worsening, continuing pain, limbs becoming very painful.
PE/03/13	**Email - Information on patient journey – *to* Welsh Mesh Survivors.**	15 October 2017	**TVT done for stress incontinence also had a rectocele repair at the same time. Performed due to issues post birth delivery.**	Wales	• **<u>Operation performed (latter end of 2007) following the delivery of son (10lb 4oz). TVT done for stress incontinence.</u>** • Suffered from mild stress incontinence and a rectocele which got worse following further births. • No risks outlined pre-op only that the operation might not work. Within days of operation incontinence issues, very poor bladder control. GP advice – need to let things settle down. • Sept 2017 went to hospital as a day patient to have some of the mesh trimmed. Following this, obtained added urinary problems. Had a colonoscopy to try and find the cause of severe abdominal pains. • Following operation had added urinary problems. Sharp sudden pain in right groin area. Constant generalised muscle pain. • Diagnosed with Fibromyalgia in 2010.
PE/03/14	**Email - Information on patient journey – *to* Welsh Mesh Survivors.**	15 October 2017	**Hysterectomy and then mesh was placed in the vagina.** **+ removal**		(*Husband of a bereaved lady*) • **<u>2008 hysterectomy, mesh was placed in the floor of the vagina, 6 months later experienced severe pain</u>**. • Developed several infections, which was not possible to get under control, ended up loosing her teeth. • Spoke to many Dr's not able to help, found a surgeon that could remove hoping that would stop the pain. Surgeon warned that the damage may have already been done but there was a slim chance it would be ok.

					• Unfortunately the pain had not gone and tried to get assistance. Sadly, the lady passed away in March 2016. Death certificate stated accidental drug overdose. Family believe the mesh caused the death even if secondary.
PE/03/15	**Email - Information on patient journey – *to* Welsh Mesh Survivors**	15 October 2017	**Implanted with a AMS Monarch +removal**	Scotland	• **Implanted with an AMS Monarch in 2006.** • Woke up from surgery couldn't feel legs. Got better, but found it difficult to move around and obtained an infection. • Back and forth to the GP to try and find a cause to the painful hips and sore groin. Told that it was 'wear and tear' and normal for age (58). • Over the following years, suffered UTIs . • **Mesh tape was removed in Nov 2016.** Resulted in an increase in nerve damage, groin and pelvic pain. Mesh tape removed in November 2016. • Remained on Sick leave and sacked from NHS (worked as a community Psychiatric Nurse). • At no point any of the risks were outlined or post surgery asked if suffering of any symptoms. • **Wanting: A retrospective study which calls on all women implants to be asked about specific symptoms and to what degree they might be experiencing those.**
PE/03/16	**Collated WALES Information *(PE-01-01) – 1***		**Colposuspension with hysterectomy and mesh**	Wales	• **Colposuspension with hysterectomy and mesh in 1997** • 2005, continually ill with severe cystitis. Started bleeding and in severe pain, no infection present. (Suffered for 5 years on and off). • Camera up the bladder and found a mass, clips and mesh had broken away and they were cutting into the bladder and bowel. Large mass had grown. • There was a need to split the bladder into four to remove the mass and bits. Lost some bowel and was in theatre for around 5 hours. In hospital for nearly a month and was in severe pain afterwards. • Left using a catheter, it has ruined the life she had with her husband.
PE/03/17	**Collated WALES information *(PE-01-01) –***		**TVT for urinary stress**	Wales	• **TVT fitted in 2017 for USI.** • Prior to the op the USI was affecting quality of life and

	2		**incontinence.** **+ removal**		consultant suggested TVT as it was a quick procedure with a fast recovery time. • Within days of TVT started to feel unwell, sickness, increasing pain and discomfort. • Referred by the GP to the local emergency Gynae Hospital. Kept in for the day and sent home with painkillers. • The pain increased that week and again referred back to the Emergency Gynae. Consultant confirmed that the mesh had started to protrude through the vaginal wall and that it needed to be removed as soon as possible. • GP had prescribed many treatments of antibiotics and Tramadol to help with the pain. • Constant pain that has a detrimental effect on mental wellbeing and suffered depression. • Had mesh removed in 2017 - considerable improvement as a result. • Surgeon had confirmed that there was mesh erosion one anchor was left as it was deemed dangerous to remove. Slight concerns about future pain.
PE/04	**Patient Experience – Detailed journey:**				
PE/04/01	Information on patient journey – (**Welsh Mesh Survivor)**	**15 October 2017**	**Minimally invasive, gold standard TVT-0 fitted for stress incontinence.**		• **<u>Minimally invasive, gold standard TVT fitted in November 2009 (age – 36) for stress incontinence.</u>** • The damage was instant. Now 44, unable to work, mostly bed bound, used a catheter and had multiple autoimmune complications. • Had multiple revision surgeries since 2011 and seriously ill with life threatening infections in 2015.
PE/04/02	**Letter** from …to the ***Health Minister Jackie Doyle Price***, and members of the Parliamentary Debate on Vaginal Mesh Implants	**14 October 2017**			

PE/05	**Patient Experience – Detailed journey:**				
PE/05/01	**Email** - Information on patient journey –to **Welsh Mesh Survivors**	**13 October 2017**	**Implanted with 0TVT-0 for stress incontinence**	England	• **<u>Implanted with 0TVT-0 for stress incontinence in 2010</u>** • Number of surgeries to find out the problem, bleeding, pain, unable to have sexual relationships, high blood pressure, thyroid diverticulitis, hot sweats and flushes. • Went to see the doctor in December to say that she could feel the mesh, went back in April and again in May as in agony. • Went to see the consultant who originally operated, waited months and paid to go private. • Sent for a transvaginal scan, told that results were fine nothing wrong. The consultant would not look or listen to her and felt very frustrated. • Went to see a consultant and once examined confirmed it was almost slicing her. • Had hours of complicated surgery as the mesh had embedded in urthera, bladder and sliced through vagina. • Now suffering after the huge operation.
PE/05/02	**Email** - *Information from the partner of …*	**14 October 2017**			
PE/05/03	**Article – '***Mesh Implants debate shows Government 'out of touch''* Carl Sargeant with **..**	**23 October 2017**			
PE/05/04	**Letter from .. to the Cabinet Secretary for Health (VG)**	**16 January 2018**			Including pictures describing the problems undergone by …. over a weekend in hospital.
PE/06	**Articles – Patient Experiences (various)**				
PE/06/01	**Article 'Western Mail'**– 'Mum says she bled every day for almost five years and blames it on a mesh implant' Information on	**25 November 2017**	**Given the pelvic implant during an operation to remove her womb and fix a**	**England**	• **<u>Given the pelvic implant during an operation to remove her womb and fix a prolapsed bowel in 2004.</u>** • Suffered complications soon after including daily bleeding. • Became incontinent, scared to leave the house. • 2005 – had an operation on the medical mesh but it didn't stop

	patient journey –**(Welsh Mesh Survivor)**		**prolapsed bowel**		the bleeding. • 2008 – Absolute agony and suffered from ulcerative colitis as the bowel was so inflamed. • Surgeons operated again and found that the mesh had disintegrated and turned hard like glass. • It had caused so much internal damage that they had to remove the entire bowel and rectum and now fitted with a colostomy bag for life. • Suffered from a series of conditions including irritable bowel syndrome and extreme acid reflux that has caused lung damage. • Also, has 3 hernias.
PE/06/02	**Article 'Wales on Sunday'** – Information on patient journey –**(Welsh Mesh Survivor)**	**3 December 2017**	**Vaginal Mesh Implant – Suffering from a urinary incontinence**		• **<u>Vaginal Mesh Implant – Suffering from a urinary incontinence</u>** • **<u>Outlined – PE/03/08</u>**
PE/06/03	**Article 'BBC' –** *'Welsh patients call for ban on vaginal mesh to treat hernias'* **– Following the journey of – .. (Welsh Mesh Survivor)**	**10 January 2018**	**Mesh used to treat hernia**	**Wales**	**Mesh used to treat hernia**
PE/06/04	**Article 'Barry and District News' '**Surgical mesh campaigner calls for Welsh Government ban on use' – Information on patient journey – **(Welsh Mesh Survivor)**	**18 January 2018**	**Polypropylene mesh was implanted following a keyhole surgery to remove gall bladder**	**Wales**	• **<u>Polypropylene mesh was implanted following a keyhole surgery to remove gall bladder</u>** • **<u>Outlined – PE/03/03</u>**
PE/06/05	**Article posted on 'Mesh Life'** (Un) Happy 4th Mesh Anniversary'.	**January 2018**	**TVTO operation, Jan 2014 to fix stress urinary incontinence following birth of 10lb son**		• **<u>TVTO operation, Jan 2014 to fix stress urinary incontinence following birth of 10lb son (third).</u>** • Living in constant pain, feeling worthless. • Now has a decision about removal – risks as mesh is too tight and the left side is implanted at an angle. Given options – cut to release tension, partial removal of the left side of full removal, all come with risks.

PE/07	**Statistics – Group**				
PE/07/01	**Welsh mesh statistics** – Mesh implants in Wales from 2006-2016 ANF Mesh removals	**2006-2016**			No information regarding the data source.
PE/08	**End of life care**				
PE/08/01	***Story of …***				• Recently had to have a colostomy and urostomy. • Suffers from an infection that is antibiotic resistant. • Mother (37) had been told to prepare her children for her death and offered an end of life mentor.
PE/08/02	Various stories with pictures of women who have passed away.				
PE/09	**Points raised by Group**				
PE/09/01	**Welsh Mesh Survivors Group – Bullet point** – Information from NWIS – figures (Transvaginal Mesh implant Procedures and Removals)	**Episode Year 2006/07 – 2016/17**			The Group suggests that there are no true figures of mesh implant procedures and removals due to under-reporting.
PE/09/02	**Welsh Mesh Survivors Group – Bullet point** – Pathway outlining 'Symptoms, Signs and Actions' and map of UK showing specialist clinics.				There are no specialist clinics for mesh injured people in Wales and expert care and equipment to treat issue including trans-labial scans
PE/09/03	**Welsh Mesh Survivors Group – Bullet point** – Mesh Helpline in Scotland				The need for a Welsh helpline in Wales
PE/09/04	**Welsh Mesh Survivors Group – Bullet point** – Letter from … at HB to patient seeking a referral to the .. from HB.				Issue regarding patient being refused cross-boarder treatment and need to ensure that Wales have consultants who are trained on expert care and treatment with specialist equipment.
PE/09/05	**Welsh Mesh Survivors Group –** Correspondence				Correspondence provides an update on the T+F Group set up and that the WG had opened a consultation on proposals to end the manufacture and

	to the Cab Sec seeking an update on progress made by the Welsh Mesh Working Group **–Use of polypropylene for surgical mesh**				sale of polypropylene plastic from June 2018.
PE/09/06	**Article -** 'The Sunday Post' 'Mesh Victim gets life-changing surgery'	**17 December 2017**			This is what the Welsh Mesh Survivors Group would want to see: **…** suffered nerve damage after doctors used metal hooks to insert a mesh implant to treat bladder problems after childbirth. – …. was offered Sacral Nerve Stimulation.
PE/10	**T+F Group/Meeting with Cab Sec**				
PE/10/01	**Email** from ***Welsh Mesh Survivors*** to the ***Chair and members of the Task and Finish Group***	**October 2017**			
PE/10/02	**The Scottish Campaign – Welsh Mesh Survivors Group**				
PE/10/03	**Excerpts of emails–** The Scottish SUI patient information leaflet and Scottish report				
PE/10/04	**Note ahead of the meeting -** Points that the Welsh mesh Survivor Support Group wish to raise	**22 January 2017**			Meeting to discuss complications of surgical mesh devises with the Cab Sec, Jane Hutt AM, Welsh Mesh Survivors Support Group
PE/10/05	**Bullet Points** from the Welsh Mesh Survivors Group. (Needs)				-Suspend Mesh use in-line with Scotland o Ban in NZ , many banned in Australia o FDA reclassified High risk category certain mesh implants o FDA reclassified surgical instruments designed to implant e.g. Trocars o EC reclassified or plans to – high risk -Mandatory reporting of Adverse Incidents by Surgeons and a guide to

					patients to report via the Yellow Care Scheme -Register of Mesh Injured people -Better training for Removal Surgeons and also training in the use of Native Tissue repairs. -Better training for GPs and Consultants to recognise Mesh Complications. -Wales currently has no Specialist Clinic set up for patients with Mesh Complications. We need expert fully informed medical staff, medical treatment and care. Expert removal Surgeons and specialist equipment – Trans-labial scans etc. -If there are to be No specialist clinics in Wales we need ease for cross-boarder funding. -Better safety measures to be put in place for women and men and can be assessed and audited. Patient Information Leaflets to be fully informative of complications, statistics and advice on the material of the mesh is made from e.g. polypropylene and to make certain that Surgical Tape/Ribbon/Sling Devise has the work MESH precedes those terms. -Mesh Helpline. -PIP Assessors to be fully informed about Mesh complications which are invisible and embarrassing. -Blue Badge Assessors as above. Possibly help to fill in the on-line forms.
PE/11	**Quotations**				
					"Our lives begin to end the day we become silent about things that matter"– Dr Martin Luther King, Jr. "First they ignore you, then they laugh at you, then they fight you, then you win" – Mahatma Gandhi

					“Trust me, I know how it feels. I know exactly how it feels to cry in the shower so no one can hear you, and waiting for everyone to fall asleep so you can fall apart, for everything to hurt so bad you just want it all to end. I know exactly how it feels” “A lie doesn’t become truth, wrong doesn’t become right and evil doesn’t become good, just because it’s accepted by a majority” “I am here to change the world. AND I AM NOT ALONE”

Research – Welsh Mesh Survivors' Group Annex 1

Ref	Type	Pub Date	Title	Study focus	Country (relates)
R/01 Research Studies					
R/01/01	Research	January 2018	**Trials of transvaginal mesh devices for pelvic organ prolapse: a systematic database review of the US FDA approval process.**	Vaginal mesh	USA
R/01/02	Research	September 2017	**Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of 92,246 women**	Vaginal mesh	England
R/01/03	Research	August 2016	**Evaluation of long-term surgical site occurrences in ventral hernia repair: implications of preoperative site independent MRSA infection**	Ventral Hernia repair	USA
R/01/04	Research	August 2015	**Patient-Report Satisfaction and Health-Related Quality of Life in TiLOOP® Bra-Assisted or Implant-Based Breast Reconstruction Alone**		
R/01/05	Research	September 2012	**Ventral hernia repair with synthetic, composite, and biologic mesh: characteristics, indications, and infection profile.**	Ventral Hernia repair	USA
R/01/06	Research	September 2012	**Post-Implantation Alterations of Polypropylene in the Human**	Use of mesh	USA
R/01/07	Research	April 2012	**Surgical complications with Synthetic Materials**	Use of Mesh	Mexico
R/01/08	Research	April 2011	**Degradation, infection and heat effects on polypropylene mesh for pelvic implantation: what was known and when it was known**	Use of Mesh	USA
R/01/09	Research	October 2010	**Polypropylene Vaginal Mesh Grafts in Gynecology**	Use of Mesh	USA

R/01/10	Research	January 2009	**Structural and thermal properties of polypropylene mesh used in treatment of stress urinary incontinence**	Use of Mesh	Brazil
R/02 Articles					
R/02/01	Article	January 2018	**Hernia patients speak of 'constant pain' due to controversial mesh procedure**	Hernia	UKA
R/02/02	Article	January 2018	**New Zealand Fully Bans Transvaginal Mesh**	Trans vaginal Mesh	NZ
R/02/03	Press Notice	December 2017	**Therapeutic Goods Administration – Actions after review into urogynaeological surgical mesh implants**	Surgical mesh	Australia
R/02/04	Article	December 2017	**There was a look in her eyes, mother's emotional torment at surgery nightmare**	Pelvic mesh	Australia
R/02/05	Press Notice	December 2017	**Medsafe introduces surgical mesh restrictions**	Surgical mesh	New Zealand
R/02/06	Article		**Surgical mesh**	Surgical mesh	New Zealand
R/02/07	Article		**Limitation of surgical mesh important step**	Surgical mesh	New Zealand
R/02/08	Article	December 2017	**New Zealand becomes first country to fully ban controversial vaginal mesh procedures**	Vaginal mesh	New Zealand
R/02/09	Article	October 2017	**Newport Hospital is the First in Wales to offer innovative internal Bra Breast Procedures**	Bra Breast procedure	UK – Wales

R/02/10	Article	October 2017	**Suspend vaginal mesh implant use in Wales, says Owen Smith**	Vaginal mesh	UK - Wales
R/02/11	Article	August 2017	**Lamborghinis, ski trips used to market controversial mesh implant to surgeons, document show**	Surgical mesh	USA
R/02/12	Article	August 2017	**Vaginal mesh campaigners welcome 'Major Development'**	Vaginal mesh	UK – NI
R/02/13	Article	August 2017	**Surgical Mesh a Decade of damage**	Surgical mesh	New Zealand
R/02/14	Article	Jan 2015	**Scandal of fruit netting 'approves as surgical implant'**	Surgical mesh	UK
R/02/15	Article		**Hernia mesh – Medtruth**	Hernia	
R/02/16	Article	July 2014	**Johnson and Johnson's 'Blue Sh*t Cover'**	Mesh	
R/03 Documents					
R/03/01	Doc	January 2018	**Surgical mesh implants – House of Commons**	Surgical mesh	UK
R/03/02	Doc	June 2017	**Obstetrical and Gynecological Devices; Reclassification of Surgical Instrumentation for Use with Uro-gynecological Surgical Mesh**	Surgical Mesh	USA
R/03/03	Doc	May 2017	**Synthetic Vaginal Mesh Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women**	Synthetic Vaginal Mesh	NHS – UK

R/03/04	Tool		**What matters to you when choosing surgery for stress urinary incontinence? Shared decision tool for patients**	SUI	UK – Scotland (Ayrshire and Arran)
R/03/05	Service		**Lothian and Greater Glasgow Mesh Complication Service**		UK – Scotland (Glasgow)
R/03/06	Guidance	Dec 2017	**NICE Guidance**	Mesh	UK
R/04 Diagrams/ Pictures					
R/05 – Scotland					Scotland

Sadly, women describe how they had to 'educate themselves on the issues' relating to the adverse effects of mesh implants and had to become their own advocate. They report that only internet searches revealed the experiences of other sufferers. They were thankful for support and information shared on social media which has led some to find experienced surgeons.

Some women describe being in excruciating pain immediately following surgery and not being able to bear weight and knowing straight after the operation that 'something wasn't right'. 'Pain in hips, thigh and pelvis' are described and being in 'terrible pain and unable to walk'. One woman describes being 'sent home after 9 days on crutches in extreme pain and with catheters'.

What we have been told:

"Being assured it was very unusual to have so much pain and UTI's. Told was 'the only one' and it couldn't possibly be the TVT. To find that another woman who had the operation on the same day, by the same consultant was also told the same."

Women reported suffering 'several severe physical side effects due to erosion and breakdown of mesh causing painful bowel and bladder problems, migration of mesh and infections'. Some reported nerves being damaged or mesh cutting into tissue and muscles, 'living in pain torture and on antibiotics and having to take morphine or opiates'. Many felt that they were experiencing foreign body allergic reactions to the plastic mesh material and that this led to memory loss and fatigue. There are reports of injuries to partners during sex. One woman reported 'growing bladder stones that contain mesh'.

The stated effects on the quality of women's daily lives from what they consider to be from the complications from synthetic mesh implants is in no way minor. Women have reported being severely disabled and being in life changing pain. They describe (in their own words):

- Chronic nerve pain to live with 24/7. No escape.
- Feeling easier to commit suicide than live in chronic pain for the rest of life.
- Pain and crying affecting relationships with children, teenagers, grandchildren.
- Having to self-catheterise 5-6 times a day, take huge amounts of pain killers and mental health and relationship has suffered.
- Pain is constant day in day out. Thoughts of suicide every day as feel a burden on family. Hating life.
- Living with indescribable pain. So many painkillers causing concern over permanent liver damage.

- Trying to manage pain on a daily basis, letting down friends in the process.
- Not seeing the point of carrying on with life as a zombie due to pain killers.
- Spending lots of money on pain management and travelling to see specialists.
- Life is a modified version of what it was. Pain killers through day and night have an effect on what can do and what feels like doing.
- Changed from being lively, bubbly character to miserable, useless, housebound, disabled and depressed with nothing to look forward to other than pain and more pain.
- Having to amend life to reduce pain. Gone from being super fit now can no longer jump or run. Exercise sets off nerve damage pain. Have to take nerve blockers.

What we have been told:

Mesh implant took away everything. Nothing left, no hope, no dreams, and just living nightmare of constant pain. Living everyday in pain destroys from the inside out. Can't remember the last time I went out or laughed. Life now consists of pottering about and lying on the settee wishing was not here. Tired and so angry, tired of constant battle to try and get someone to listen and help. Angry was lied to and are still lying. Most days just sad, sad that was a fool to allow them to do this, sad no one will help, sad that I hurt where no one should hurt.

Women describe their feelings and emotions in relation to how they their life has changed following synthetic mesh surgery:

- 'Life has been ruined. Have no life'.
- 'Life being changed from a normal happy life to a dread of everyday existence'.
- 'Sleepless nights worrying what the mesh is doing to my body and what the future holds'.
- 'Having to use a wheelchair to go out, can't sit for long, can't stand for long'.
- 'Lost everything, husband, home and independence.'
- 'No longer able to participate in sporting tournaments, riding, exercise classes, bike riding, everyday activities such as shopping, walking the dog, housework left to others.'
- Developed scalp and nail psoriasis. 'Head is permanently inflamed and nothing will get rid of the itch and flaking. Recently diagnosed with fibromyalgia, whole body stiff and inflexible'.

- ‘Life is exhausting. Trying to maintain usual jolly outlook but have really lost ‘mojo’. Everything has to be considered before hand. Cannot go trekking or walking with the family.’

- ‘Depressed angry and miserable and lost a lot of friends. There is no life after mesh.’

- ‘Recovery is long. Having to take medication for nerve damage. Lost years of life being zapped of energy and drawn down into depressions.’

- ‘Walking like a 90 year old. Complex operation and finding that mesh had adhered to bowel as well as eroding into the vaginal vault. Having to be careful what to eat and not sure when will be able to return to work.’

- ‘Destroyed years for women and families. Not being fun to be with, always feeling weak and in pain, septicaemia, acute pyelonephritis, continuous UTIs and low grade fevers.’

- ‘Lost pride and dignity. Scared to go out in case anyone sees with a walking aid. Panic attacks and insomnia. Constant pain 24/7 and not coping well.’

- ‘Daily care of grandchildren a struggle.’

Many women reported a strain on personal relationships with their partners, family and friends and many women reported having difficulties with or lost their sex lives.

Women report that they can no longer work on a regular basis, and some have had to give up careers. Some quotes from testimonials received are:

- ‘Told to go back to work when mesh had embedded itself onto remaining bowel (half of which removed) abdominal wall and organs’.

- ‘Leave of absence from work is adding to the terrible guilt felt all the time for putting family through this.’

- ‘A couple of days off work for the operation turned into twelve weeks. Constant UTI’s with stronger and stronger antibiotics being prescribed one after the other along with stronger pain killers. The ‘walk of shame’ when told to go home by the boss when returned to work because felt boss was thinking she was ‘taking advantage’.’

Due to the complexity and difficulty of mesh removal many women report ‘living with little hope’ as it is known that removal does not always resolve issues and can ‘make things worse’. In addition a few women describe difficulties in finding it hard to find a surgeon experienced in full mesh removal and for this to be funded by the NHS. Welsh women were generally unaware of any centres of expertise in Wales. They specifically have concerns about the imaging technology being used and the fact that

mesh is not MRI opaque and therefore very difficult to visualise. Those women who have undergone procedures to correct or remove mesh recount experiences of:

- ‘Cannot sit down properly or walk, in so much pain. Removal surgery left with terrible burning, nerve damage and scar tissue.’
- ‘Several painful operations and surgical procedures to remove mesh.’
- ‘Over 14 years - operations and countless painful and undignified procedures and investigations.’
- ‘Adverse event during mesh removal operation has led to additional serious and life changing condition.’
- ‘Very complicated surgery for removal often with complications, infections and long recovery.’

Annex 3

Methodology for Welsh Data on Mesh Implant and Removal:

These figures provide a count of the number of finished consultant episodes in which a specific procedure has been recorded as being undertaken, and the number of patients who have undergone any of these procedures. Any given patient may be responsible for the appearance of more than one incidence of a procedure or procedures - for example if they had an implantation, followed by one or more partial removals and then a total removal.

The figures include all *procedures* carried out for stress incontinence, vaginal or uterine prolapse in which mesh or tape has been inserted, removed or over-sewn only when one of the following applied:

1. The words 'mesh' or 'tape' is included in the OPCS descriptor for the procedure.
2. The codes are present on NHS Digital, Table of Coding Equivalence for any of the procedures in point 1. The NHS Digital, Table of Coding Equivalents provides details of changes in OPCS Classification code(s) that have occurred due to the release of any new version of the classification.
3. There is a specific Clinical Coding Standard with direct instructions on how to record one of the procedures covered by this report.

The Classification Team acknowledges that it is possible that mesh could have been inserted during procedures that are not included in these figures. However, it is not possible to use clinical coded data to identify these procedures.

The figures on these procedures have been divided into three distinct sections:

1. Procedures that include the implantation of mesh or tape
2. Procedures that include removal of mesh or tape (both Partial and total removal)
3. Over-sewing of any exposed mesh or tape in the vagina

The NWIS Classification and terminology team would like to clarify that it is not possible to identify the type of mesh implanted (prosthetic) (biological) using historical clinical coded data. However, the team with the assistance of interested clinicians is in the process of drafting a new Welsh Clinical Coding Standard. In the future, if the type of mesh used has been documented within the medical record the use of this proposed standard should allow easy identification of the type of mesh used. It is hoped that this new standard will be mandated for use by the Clinical Coding Service in NHS Wales on any finish consultant episode (FCE) with an end date on or after 1st April 2018.

It should be noted that these figures include a range of recognised complications related to this type of surgical procedure and do not necessarily indicate a fault with any particular device. They include reports from manufacturers, healthcare professionals and members of the public. It should also be noted that reported incidents may not necessarily represent an individual patient and because there is no limiting time on reporting, trends need to be interpreted using other data.

UK for all mesh (not defined by indication of use)

Years	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	**Grand Total**
Count of Incident Number	26	5	12	12	41	52	99	106	276	392	265	**1,286**

Reports of adverse incidents received from Wales 2011-2017

Implants, Non Active, Implantable Incontinence and Prolapse Devices	**2011**	**2014**	**2015**	**2016**	**2017 (YTD)**	**Total**
Vaginal Mesh For Incontinence	<=5		<=5	<=5	30	38
Vaginal Mesh For Prolapse	<=5	<=5	<=5	<=5	15	19
Vaginal Mesh~ Unknown Indication					<=5	<=5

<=5 indicates that the numbers were less than or equal to 5. In order to comply with our confidentiality obligations we are unable to provide further detail due to the low number of incidents reported. The information above is the data that we are able to provide at the moment.

Annex 5

Data and information Repository – Vaginal Meshes and Tapes – December 2017

No.	Publication	Date	Attachment
1.	All Wales Bladder/Bowel Care Pathway	2006	 All Wales Bladder and Bowel Care Path
2.	GMC consent guidance	2 June 2008	http://www.gmc-uk.org/Consent___English_0617.pdf_48903482.pdf
3.	NICE Audit Support – Surgical Repair of vaginal wall prolapse using mesh	2008	 NICE audit-support-Surgica
4.	HTA - Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence	2010	 Economic model of non surgical treatmen
5.	Guerrero, K.L., Emery, S.J., Wareham, K., Ismail, S., Watkins, A., & Lucas, M.G. 2010. A randomised controlled trial comparing TVT, Pelvicol and autologous fascial slings for the treatment of stress urinary incontinence in women. *BJOG: An International Journal of Obstetrics & Gynaecology*, 117, (12) 1493-1502.	2010	https://www.ncbi.nlm.nih.gov/pubmed/20939862
6.	International Urogynecological Association (IUGA)/ International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery	January 2011	http://onlinelibrary.wiley.com/wol1/doi/10.1002/nau.21036/full
7.	FDA guidance	July 2011	https://www.fda.gov/downloads/medicaldevices/safety/alertsandnotices/ucm262760.pdf
8.	York University Health Economics Consortium:	2012	http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con205383.pdf

	Summaries of the Safety/Adverse Effects of Vaginal Tapes/Slings/Meshes for SUI and Prolapse		
9.	Mesh 6 year retrospective study published in IUGA Meeting Abstract – 6 year retrospective audit of clinical and subjective outcomes of original vaginal prolapse repair with the insertion of mesh, UHW and Prince Charles Hospital.	2012	 Mesh Audit published in IUGA - 6 year retrc
10.	Letter from Sir Bruce Keogh to Medical Directors in England	November 2012	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213189/Vaginal-tapes-and-meshes-letter-to-NHS-final1.pdf
11.	Better guidance and support for NHS surgeons on vaginal tape and mesh implants	22 November 2012	https://www.gov.uk/government/news/better-guidance-and-support-for-nhs-surgeons-on-vaginal-tape-and-mesh-implants
12.	SMO's letter	28 January 2013	 Vaginal Tapes - MO letter.pdf
13.	FDA information for Patients for SUI	last updated 23 March 2013	https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/urogynsurgicalmesh/ucm345230.htm
14.	Excel copy of NICE Audit	September 2013	 Copy of NICE clinical-audit-tool-exc
15.	Welsh Government Statement – Management of Urinary Incontinence in Women	February 2014	 Welsh Government Statement - February
16.	SMO's letter	13 February 2014	 Vaginal Tapes - SMO letter Feb 14.pdf
17.	Spire briefing – Pelvic Mesh Product – TVT	July 2014	 Spire briefing - Pelvic Mesh Product (TVT) J
18.	Spire Patient Information Leaflet		 Spire Healthcare Vaginal Tape Insertio
19.	Patient Safety Notice PSN002/18 July 2014	18 July 2014	 Meeting Paper xxx Meeting ...

20.	MHRA – Vaginal Mesh Implants: Summary of Risks and Benefits	28 October 2014	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/402162/Summary_of_the_evidence_on_the_benefits_and_risks_of_vaginal_mesh_implants.pdf
21.	Khan ZA, Thomas L, Emery SJ. Outcomes and complications of trans-vaginal mesh repair using the Prolift™ kit for pelvic organ prolapse at 4 years median follow-up in a tertiary referral centre. Arch Gynecol Obstet. 2014 Dec; 290(6):1151-7.	December 2014	https://www.ncbi.nlm.nih.gov/pubmed/24981047
22.	Khan ZA, Nambiar A, Morley R, Chapple CR, Emery SJ, Lucas MG. Long-term follow-up of a multicentre randomised controlled trial comparing tension-free vaginal tape, xenograft and autologous fascial slings for the treatment of stress urinary incontinence in women. BJU Int. 2015 Jun; 115(6):968-77.	June 2015	https://www.ncbi.nlm.nih.gov/pubmed/24961647
23.	NICE guidance	last updated November 2015	https://www.nice.org.uk/guidance/cg171
24.	Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR) - European Commission	3 December 2015	https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_049.pdf
25.	BSUG website containing patient information leaflets for BSUG, BSUG and NHS, RCOG, and IUGA	date unknown	http://bsug.org.uk/pages/information-for-patients/111
26.	Cochrane Review	9 February 2016	http://www.cochrane.org/CD012079/MENSTR_transvaginal-mesh-or-grafts-compared-native-tissue-repair-vaginal-prolapse
27.	PROSPECT study	Lancet 28 January 2017	 PROSPECT Report.pdf
28.	Joint BSUG, NHS and Royal College of Obstetricians and Gynaecologists - Surgical procedures for Treatment of Pelvic Organ Prolapse in Women – Patient Information Leaflet	May 2017	 POP Mesh Leaflet V11 BSUG RCOG logo

29.	Joint BSUG, NHS and Royal College of Obstetricians and Gynaecologists - Synthetic Vaginal Mesh Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women- Patient Information Leaflet	May 2017	 SUI Mesh Tapes Leaflet Version 24_16
30.	Mesh Oversight Group Report	July 2017	 mesh-oversight-grou p-report - July 2017.p
31.	Mesh Oversight Group Report – GP Resource	July 2017	https://www.england.nhs.uk/publication/information-for-health-professionals-on-mesh-implants/
32.	Welsh NHS Consent guidance and Forms	24 July 2017	http://www.wales.nhs.uk/governance-emanual/patient-consent/
33.	MHRA – Yellow card data and breakdown for Wales	as at October 2017	 MHRA Yellow Card Information 2006 to 2
34.	PEDW data for Wales on procedures undertaken	as at October 2017	 Table of procedures in Wales - Meshes an
35.	Welsh procurement information	as at October 2017	 TVT summary of spend by supplier 20(
36.	Transcript of Westminster Hall debate	18 October 2017	http://hansard.parliament.uk/commons/2017-10-18/debates/B546B1F1-099F-442C-AD71-0185D1B3F69C/SurgicalMeshImplants
37.	Australian Government – Therapeutic Goods Administration actions after review of urogynaecological surgical mesh implants	28 November 2017	https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants
38.	Literature Search – Pain - Sue Jenkins, School of Medicine, Cardiff University	December 2017	 Literature search findings.xlsx
39.	Explain Pain video		https://youtu.be/C_3phB93rvI
40.	Tame the Beast video - Prof Lorimer Moseley		https://youtu.be/XwBYkw-iZdQ
41.	Neuralgia – What is nerve pain and how to cope with it		https://youtu.be/8aVaiH92OtM?t=73
42.	Pain Toolkit		https://www.paintoolkit.org/

43.	Enhanced Physiotherapy Report	December 2017	 Enhanced Physiotherapy Report
44.	All Wales Physiotherapy Provision	December 2017	 All Wales. WH Physio provision_.pdf
45.	Literature Search – Physiotherapy Effectiveness for Management of Vaginal Prolapse and SUI	December 2017	 Literature Search for MESH Group 2017.xls
46.	BMJ – Transvaginal mesh failure: lessons for regulation of implantable devices	7 December 2017	http://www.bmj.com/content/359/bmj.j5515
47.	NICE interventional procedure guidance (IPG 599) Transvaginal mesh repair of anterior or posterior vaginal wall prolapse	15 December 2017	https://www.nice.org.uk/guidance/IPG599
48.	Pain Reports : Risk stratification for the development of chronic post surgical pain	2017	 Risk_stratification_for_the_development_(
49.	European Commission Report		
50.	Scottish Reports Interim and Final		 final Scottish Report March 2017.pdf
51.	House of Commons - Briefing Paper – Surgical Mesh Implants	15 January 2018	http://researchbriefings.files.parliament.uk/documents/CBP-8108/CBP-8108.pdf
52.	Supplementary advice by TGA in Australia	17 January 2018	https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants
53.	Pelvic Floor Society		http://thepelvicfloorsociety.co.uk/
54.	Pelvic Floor Society Statement		 Pelvic Floor Society statement on use of r

Publications awaited

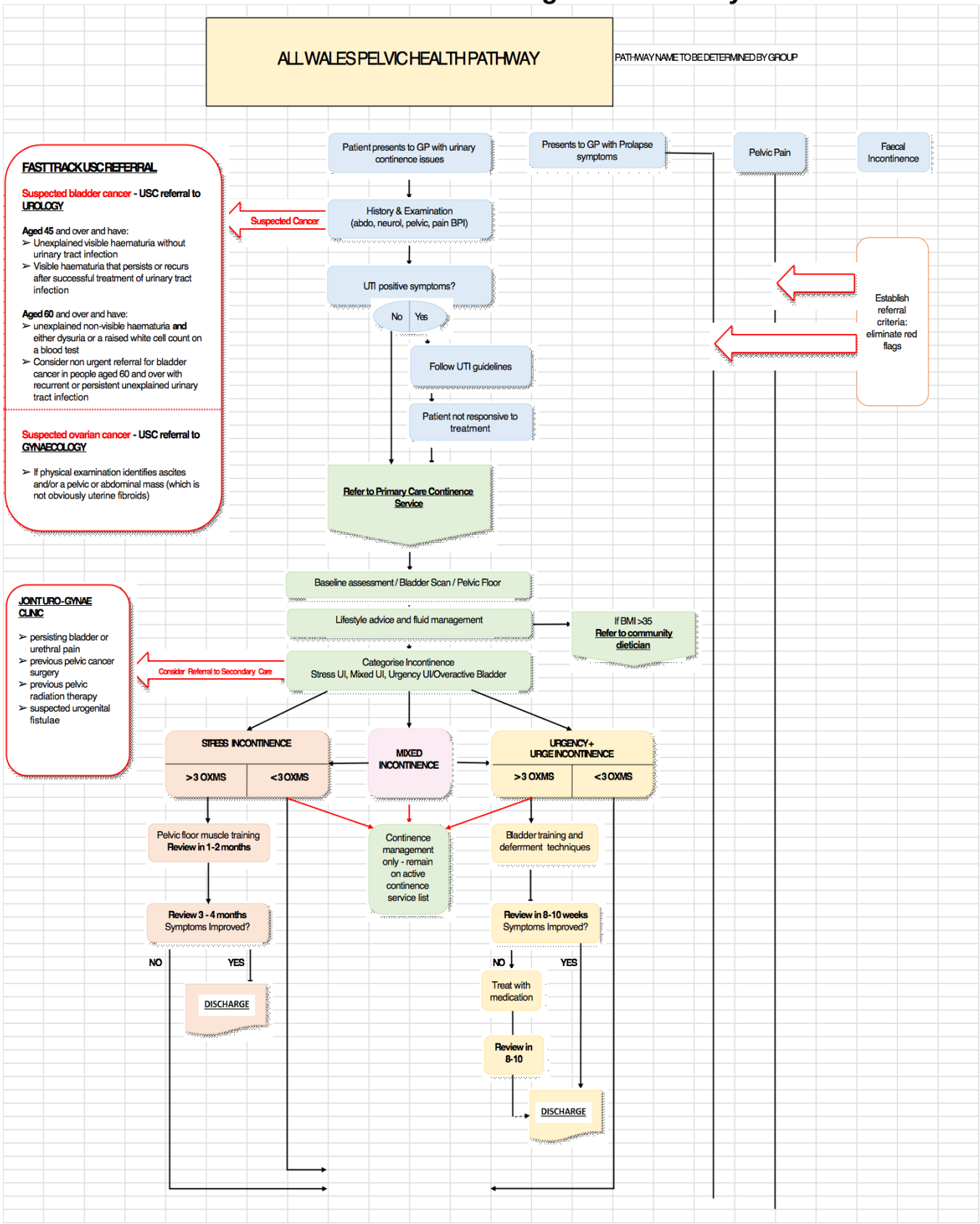
2.	NICE guidelines- Urinary Incontinence (update) and Pelvic Organ Prolapse: Management guideline	Expected February 2019
3.	MHRA Report – The use of Polypropylene Mesh in Stress Urinary Incontinence and Pelvic Floor Reconstructive Surgery – a review of biocompatibility	To be available 2019

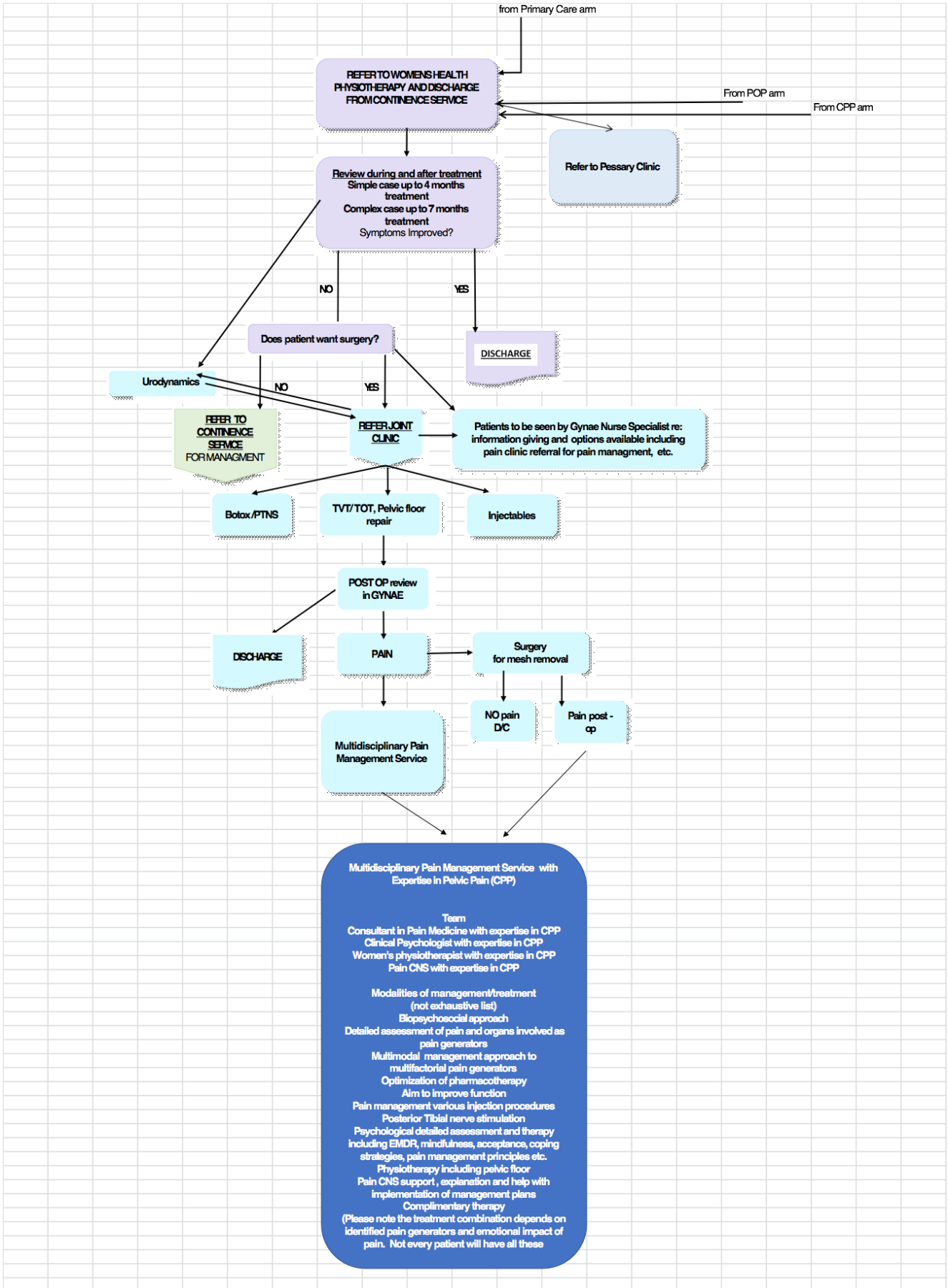
Audits in Wales

1.	Cwm Taf Audit – Prince Charles Hospital (March 2013)	 Mesh Repair Audit Cwm Taf Prince Charl
2.	Cwm Taf Audit – Royal Glamorgan Hospital (July 2016)	 Mesh repair Audit Cwm Taf Royal Glam
3.	BCU Audit – Ysbyty Gwynedd (received 27 October 2017)	 ICIEG World Congress 2018d ...
4.	Survey by Nadia Bahl (December 2017)	 All Wales survey - December 2017 - Nac  All Wales Survey- December 2017 - Nac
5.	Summary Table - Medical Director responses to DCMO	 Medical Director responses re Meshes
5a	Medical Director Response – Aneurin Bevan	 2017 12 07 - Response - MESH.xls:  2017 12 07 - Respons NHarris - ME
5b	Medical Director Response – ABMUHB	 TVT response to Chris Jones 13.11.17
	Medical Director Response – BCUHB	 2017-11-08 EM Letter.pdf  Mesh Use by Surgeons Gynaecolog
5c	Medical Director Response – Cwm Taf	 Surgical Management of Urinary Incontinen  Surgical Management of Urinary Incontinen
5d	Medical Director Response – C&VUHB	 Chris Jones surigal mesh.doc
5e	Medical Director Response – HDUHB	 Letter Dr Chris Jones re Surgical Mesh 4.12
5f	Medical Director Response – Powys	 Response Letter Professor CJ - Surgica

Annex 6

Draft All Wales Pelvic Heath And Wellbeing Care Pathway




from Primary Care arm
REFER TO WOMENS HEALTH PHYSIOTHERAPY AND DISCHARGE FROM CONTINENCE SERVICE
From POP arm
From CPP arm
Refer to Pessary Clinic
Review during and after treatment
Simple case up to 4 months treatment
Complex case up to 7 months treatment
Symptoms Improved?
NO
YES
Does patient want surgery?
DISCHARGE
Urodynamics
NO
YES
REFER TO CONTINENCE SERVICE FOR MANAGMENT
REFER JOINT CLINIC
Patients to be seen by Gynae Nurse Specialist re: information giving and options available including pain clinic referral for pain managment, etc.
Botox /PTNS
TVT/ TOT, Pelvic floor repair
Injectables
POST OP review in GYNAE
DISCHARGE
PAIN
Surgery for mesh removal
NO pain D/C
Pain post - op
Multidisciplinary Pain Management Service
Multidisciplinary Pain Management Service with Expertise in Pelvic Pain (CPP)
Team
Consultant in Pain Medicine with expertise in CPP
Clinical Psychologist with expertise in CPP
Women's physiotherapist with expertise in CPP
Pain CNS with expertise in CPP
Modalities of management/treatment
(not exhaustive list)
Biopsychosocial approach
Detailed assessment of pain and organs involved as pain generators
Multimodal management approach to multifactorial pain generators
Optimization of pharmacotherapy
Aim to improve function
Pain management various injection procedures
Posterior Tibial nerve stimulation
Psychological detailed assessment and therapy including EMDR, mindfulness, acceptance, coping strategies, pain management principles etc.
Physiotherapy including pelvic floor
Pain CNS support , explanation and help with implementation of management plans
Complimentary therapy
(Please note the treatment combination depends on identified pain generators and emotional impact of pain. Not every patient will have all these

Annex 7

Literature Search: Physiotherapy Effectiveness for Management of Vaginal Prolapse and Stress Urinary Incontinence

Nov-17 Gillian McCabe

Author(s)	Date	Title	Published In	Primary Condition	Comments	Overall Conclusion(s)
Hay-Smith et al	2008	Pelvic floor muscle training (PFMT) for urinary incontinence in women (Review)	Cochrane Collaboration	UI	Withdrawn and split into 5 reviews	N/A
Hay-Smith et al	2011	Comparison of approaches to pelvic floor muscle training for urinary incontinence in women	Cochrane Collaboration	UI	Group + Individual supervision = 90% improved	Women should be offered regular and repeated contact with the person that taught them the to do the exercises as this will likely lead to greater improvement
					Individual only = 57% Improved	
					Weekly or twice weekly supervision gained greatest improvement	
					Multiple differences in approaches to physiotherapy	
					Some interventions not adequately described	
Ayeleke et al	2015	Pelvic floor muscle training added to another active treatment versus the same active treatment alone for urinary incontinence in women (Review)	Cochrane Collaboration	UI	Quality of evidence was low or very low with the majority of trials not reporting the primary outcomes specified in the review (cure, improvement or QOL)	Insufficient evidence to state whether or not there were additional effects by adding PFMT to other active treatments when compared with the same active treatment alone for urinary incontinence in women
Dumoulin et al	2014	Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women	Cochrane Collaboration	UI	PFMT groups were 8x more likely to report a cure and 17x more likely to report a cure or improvement than the control groups	The review supports the widespread recommendation that PFMT be included in first line conservative management programmes for women with any type of urinary incontinence
					PFMT group were more satisfied and less likely to search for alternative treatments	
					PFMT group leaked urine less often, lost smaller amounts on pad tests and emptied bladders less often during the day	
					Sexual outcomes were also better in the PFMT groups	
					Few adverse effects reported, none serious	
Labrie et al	2013	Surgery versus physiotherapy for SUI	The New England Journal of Medicine	SUI	Surgery was more effective in producing an improvement in symptoms than physiotherapy alone	Moderate to severe stress urinary incontinence has a significantly better subjective and objective outcomes at 12 months after surgery than physiotherapy. Due to the adverse outcomes related to surgery, decision making should be left to the individual (informed decision making).
					Surgery risks adverse events which physiotherapy does not	
					Physiotherapy took between 4-10 months to complete	
					Some patients had already tried physiotherapy prior to being included in this study	
					Outcomes were similar after physiotherapy and for initial surgery	
Labrie et al	2014	Predicting who will undergo surgery after physiotherapy for female stress urinary incontinence	The International Urogynacological Association	SUI	It is possible to predict the likelihood of crossing over to surgery through the following variables: Age <55yrs, severe baseline incontinence complaints (measured by Sandvik-Index, PGI-S) & higher educational level	External validation of the tool is necessary prior to full acceptance and use
					This trial was on an arm of another larger randomised trial (PORTRET Study)	Use of the tool could improve insight into the best possible option for initial treatment
					The more severe the symptoms, the greater the likelihood of crossoveer to surgery	Women should be able to choose either physiotherapy or surgery as initial treatment for SUI after adequate counselling
					Women scoring <5 points could be counselled more towards physiotherapy, women scoring >10 points could be counselled more towards initial surgery	
					Scoring 5-10 points was most common and came with a chance of crossover at 32-62%: In these cases it was suggested that personal preference after adequate counselling may play a more important role	
					The tool has not yet been validated	

Current Physiotherapy provision in Wales (2017) **Annex 8**

In attempting to assess the need for pelvic physiotherapy provision in Wales the following statistics were considered. As of 2016, the female population in Wales from 16 years old and above was estimated at 1.278 million (Welsh Government, 2017)[13]. Statistics suggest that half of the female population will experience symptoms of urinary incontinence during their lives, but only one in five will seek help (Allanda, 2017)[14]. This may equate to approximately 639,000 women experiencing symptoms at some point in their lives and 127,800 of these seeking help from their health board in Wales. Approximately one in 12 women living in the community in the UK report the symptoms of pelvic organ prolapse, and of those there is a 12-19% risk of surgical intervention (BMJ, 2016)[15]. In Wales this could equate to approximately 200,000 women experiencing symptoms of POP and over 25,000 at risk of surgery at some point in their lives. Although it is impossible to transfer these lifetime statistics to produce a formula for year on year physiotherapy service provision there is clearly a disparity in the funding of physiotherapy compared to the population density covered by each health board.

The range of available services in each health board also varies. All health boards provide outpatient uro-gynaecology and obstetric services, only 3 health boards provide services for colorectal patients and one health board does not provide a service for pelvic pain. It is essential that all potential patients in Wales have the same access to the same services. All physiotherapy departments are working hard to reduce waiting lists, but this is only possible within the available resources.

In Wales there are currently 17 physiotherapists working in women's health. (The spread of these resources across each health board can be seen in the table below. As can be seen the whole time equivalents in each health board vary greatly even for health boards of a similar population. The affect this has on the waiting list in each area is also clear.

Recruitment is also an issue in some areas as is appropriate succession planning. Without adequate succession planning and human resource resilience, retirement and maternity leave or sick-leave are the greatest threats to the current workforce. (

[13] Welsh Government (2017) Mid-year population estimates (1991 onwards), by Welsh local authorities, English regions and UK countries, for single year of age and gender [online] Stats Wales accessed 4th December 2017 from https://statswales.gov.wales/Catalogue/Population-and-Migration/Population/Estimates/nationallevelpopulationestimates-by-year-age-ukcountry

[14] Allanda (2017) Some Statistics about Urinary and Faecal Incontinence. [online] accessed 4DEC2017 from https://www.allaboutincontinence.co.uk/incontinence-statistics

[15] BMJ (2016) Pelvic Organ Prolapse [online] accessed 4DEC2017 from http://www.bmj.com/content/354/bmj.i3853

ALL WALES WH PHYSIO PROVISION	C&V UHB	ABMU LHB	Hywel Dda UHB	POWYS	Cwm Taf UHB	BCUHB	Aneurin Bevan UHB
Number of Full Time equivalent staff working under the remit of women's / pelvic / men's health	4.5 WTE	1.76 WTE	1.2 WTE	.48 WTE	2.6 WTE	1.6 WTE 7	3 WTE
Services provided							
Outpatient Urogynaecology	Y	Y	Y	Y	Y	Y	Y
Outpatient Obstetrics	Y	Y	Y	Y	Y	Y	Y
Outpatient Group Classes	Y	Y	Y	Y	Y	Y	N
Inpatient Obstetrics	Y	N	N	N	N	N	N
Inpatient Urogynaecology	Y	N	N	N	N	N	N
Outpatient Colorectal	N	N	Y	Y	N	Y	N
Inpatient Colorectal	Y	N	N	N	N	N	N
Oncology (women's health - breast, gynae etc)	N	N	N	Y	N	N	N
Men's health	Y	N	N	Y	N	Y	Y
Chronic Pelvic Pain	Y	Y	Y	Y	N	Y	Y
Other services	vulvodynia clinic	vulvodynia clinic	N/A	-	-	vulvodynia clinic	-
What level of funding do you have at present - HR (number of physio's at what banding, number of support staff, number of administrative staff), training funds, equipment funding etc?	WTE 8,WTE 7, WTE 6 JOB SHARE, WTE 5 ROTN	1.76 WTE 7 .25 WTE 6, .64 SEC	0.5 WTE 7, 0.7 WTE 6	0.48WTE 7	1 WTE 7, 1.4 WTE 6, 0.2 BAND 5	1.6 WTE 7	1 WTE 7, 2 WTE 6
Do you have succession planning for posts that are currently filled with members of staff due to retire in the next 3-5 years?	Y	N	N	N	Y	N	N
What are your waiting lists for each area?	2 OBS-8 GC WKS	8MTHS	3-20WKS	2-3 WKS	2-3WKS CLASS, 1: 1 AX 4-8WKS	13 WKS	7-12 WKS
MDT	Y	Y	Y	N	N	N	Y

Annex 9

Pelvic Health and Wellbeing Pathway – Proposal for an Enhanced Physiotherapy service

- **Early referral to a minimum 3 month physiotherapy programme is recommended**

A patient identified to have symptoms of vaginal prolapse or urinary incontinence, however mild the symptoms, should be immediately referred to physiotherapy services for a minimum of 3 month pelvic floor muscle training, as specified in the NICE clinical guidelines for urinary incontinence in women (NICE, 2017)[16]

- **Avoid mentioning surgical options at the early stages of referral.**

At this initial stage, it is recommended that surgery would not be mentioned as an option by the referring agent, unless the patient specifically requests such information. The referral to physiotherapy and subsequent completion of a course of treatment should be made mandatory rather than optional prior to further, more invasive interventions. Compliance to physiotherapy programmes are likely to be enhanced through reduced options, especially those holding a "quick fix" nature in the minds of the patients.

- **Adopt the PURE pathway across Wales and see the results!**

According to a study undertaken in Cardiff & Vale UHB, direct referral to physiotherapy for those with uro-gynaecological problems, rather than waiting on a consultant's list, cut waiting times dramatically, improved clinical outcomes with conservative management and reduced the need for consultant review, therefore reducing the consultant's waiting list and enabling him to focus on the cases specifically requiring his expertise and intervention (Broad, 2010)[17]. During the study the physiotherapist took on 450 patients over a twelve month period, assessing and treating as per physiotherapy standard procedure. Of these 450 patients, only 56 (12%) were referred on to the consultant following completion of physiotherapy, 396 (88%) were successfully managed within the department of physiotherapy, not requiring medical investigation or treatment. The consultant waiting list was reduced in this time from 11 months to 3 months. This patient centred pathway has now been adopted by the physiotherapy and uro-gynaecology departments in Cardiff and Vale UHB We strongly recommend that this same pathway is adopted throughout Wales as a whole, using it as a standard of referral and treatment for those with uro-gynaecological conditions.

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[16] NICE (2017) Urinary Incontinence in Women: Management. **CG171**. Published 11 September 2013. Available online: nice.org.uk/guidance/cg171. Pp 11 & 15-17.

[17] Broad C (2010) Physiotherapy Urogynaecology Rehabilitation Pathway: The PURE Pathway. Journal of the Association of Chartered Physiotherapists in Women's Health. Spring 2011. 108, pp 16-17.

- **Additional psychological support could be key for those with anxiety and depression.**

According to a study completed by the women's health physiotherapy team in Singleton Hospital and in connection with the Psychology Department of Swansea University, it has been found that depression and anxiety can have a significant negative impact on a woman's adherence to and compliance with a physiotherapy exercise programme for pelvic floor muscle training (Wales Online, 2015)[18]. Using physiotherapy along with the adjunct of psychological support for those at high risk of depression and anxiety, compliance, motivation and outcomes can be improved, with a reduction in the need for surgical intervention. Further improvements in compliance and outcomes may therefore be found through the addition of psychological support for those indicated as high risk for anxiety and depression. It should be possible to manage the low risk patients within the physiotherapy department itself.

- **Providing a sustainable and wide ranging pool of expertise is essential for future services**

It was recommended that all health boards should be able to provide sufficient support, training and succession planning so that the service provided is of a high standard and is sustainable over many years. This requires a range of posts available from band 5 though to band 7 / 8a, funding for specialist external training for those in higher banded posts and especially those seeking to set up a women's health service with little or no experience/training.

- **Intensive physiotherapy with adjunctive treatments is more effective than basic pelvic floor training**

According to Imamura et al (2010)[19] delivering physiotherapy for pelvic floor muscle training in a more intensive fashion, with extra sessions and the addition of biofeedback is the most effective treatment.

The group recommended a patient pathway of receiving lifestyle advice and intensive pelvic floor muscle training first and then followed with surgery if required, provided the best improvement rates. The details of the 'intensive physiotherapy' programme were not discussed, other than the provision of 'extra sessions' and the use of biofeedback. The physiotherapy programmes providing 'extra sessions often reported that the patient attended the clinic more than 2 times per month. /the average length of a complete physiotherapy programme was 4.38 months.

[18] Wales Online (2015) Hospital working on a scheme to empower women. Health Check Wales. [online] accessed 5th December 2017 from: www.csp.org.uk/sites/files/csp/secure/mair_whittall_article_2015.pdf

[19] Imamura M, Abrams P, Bain C, Buckley B, Cardozo L, Cody J, et al. Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence. Health Technol Assess 2010;14(40). https://pdfs.semanticscholar.org/2154/0ee4c2b71a3cecdca9e0fa1a85672935b340.pdf

The effect of providing such extra session on waiting lists can be dramatic within the NHS setting. The effect needs to be analysed and further resources will likely be needed in order to provide such a level of care. However, if this leads to improved outcomes and reduced need for medical input, the cost benefits in the long term will be clear.

- **Physiotherapy expertise and training**

Physiotherapists themselves have a duty to provide high quality and evidence based interventions. It is therefore important that each physiotherapist is able to prove their competency, skill level and expertise appropriate to their pay scale. It is recommended that this training is placed in a more formal structure in order to protect those physiotherapists in post and also to protect patients accessing this care.

In locations where there is no or limited service, whether due to a lack of succession planning or due to unforeseen circumstances, it is suggested that a basic level of training should be provided for any new members of staff taking on the role of women's health physiotherapist.

Rotational band 5 and 6 physiotherapists can receive in-service training from more experienced members of staff through a formal training and mentoring structure within their rotation. A band 6 physiotherapist in a static and permanent position should be eligible to receive external specialist training via Pelvic, Obstetric and Gynaecological Physiotherapy (POGP) or the University of Bradford extended courses as they are relevant to the needs of their specific post. Band 7 and 8 physiotherapists should provide the majority of training to those less experienced in their department. These higher grade physiotherapists should be trained in extended scope areas as deemed necessary through appraisal and continuing professional development. The team leader or highest level physiotherapist should attend relevant conferences, such as POGP annual conference, in order to keep up to date with any changes to current practice and advice.

The above scenario could be provided in the health boards where there is such a workforce, however in smaller health boards this may need to be completed in liaison with other larger health boards. This should avoid the risk of isolation and lone working in smaller departments.

LIST OF ABBREVIATIONS

MDT	Multi-disciplinary Team
MRI	Magnetic Resonance Imaging
MHRA	Medicines and Healthcare Products Regulatory Agency
POGP	Pelvic, Obstetric and Gynaecological Physiotherapy
POP	Pelvic Organ Prolapse
SUI	Stress Urinary Incontinence
TVT	Transvaginal Tape
UDIs	Unique Device Identifiers
USC	Urgent Suspected Cancer
WTE	Whole Time Equivalent

GLOSSARY OF TERMS

OPCS Office of Population Census and Surveys. OPCS is also known as Classification of Interventions and Procedures and is the procedural classification used by clinical coders in the NHS. The OPCS codifies operations, procedures and interventions performed during inpatient stay, day case surgery and some outpatient treatments in NHS.

ICD10 - International Statistical Classification of Diseases and Related Health Problems 10th Revision) classifies diagnoses whereas OPCS classifies procedures and interventions.

CE Marking is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.

NICE interventional procedures guidance - represents best clinical practice and NHS organisations and healthcare professionals are expected to take them fully into account in the treatment of NHS patients. (To note: these must be implemented in Scotland)

IUGA: The International Uro-gynecological Association (IUGA) is dedicated to global advancement of uro-gynecological knowledge and patient care through education and the promotion of basic and clinical research on disorders of the female pelvic floor. In addition to holding an annual conference and publishing the International Uro-gynecology Journal, IUGA activities include conducting education programs around the world, developing consensus terminology in the field, connecting related professionals and producing patient education materials.

IUGA was founded in 1975 and has organized scientific meetings every year in nearly every corner of the world to promote the exchange of uro-gynecological information to thousands of physicians and healthcare providers.

EIDO: Experts in Informed Consent –EIDO is a UK company that provides patient information to health boards in a standardised and centrally available form with Plain English accreditation.

Physiotherapy: The Chartered Society of Physiotherapy (CSP) describe physiotherapy as a method of helping people affected by injury, illness or disability through movement and exercise, manual therapy, education and advice. Physiotherapists help to maintain the health of people of all ages, assisting patients in the management of pain and the prevention of disease. CSP, 2013)[20]

[20] CSP (2013) What is Physiotherapy? Published online [2013] http://www.csp.org.uk/your-health/what-physiotherapy