The Independent
MEDICINES & MEDICAL DEVICES
Safety Review

# The Independent Medicines and Medical Devices Safety Review

## Written Evidence

## Patient Groups: Pelvic Mesh

Published December 2018
Updated October 2019

# Contents



**Disclaimer**

The statements made and the opinions expressed in response to the Independent Medicines and Medical Devices Safety Review's ('IMMDSR) Call for Evidence and in the video recording of the IMMDSR's oral hearings are those of the authors. They do not purport to reflect the opinions, views or conclusions of the IMMDSR or its members. The statements and opinions made do not imply the expression of any opinion whatsoever on the part of the IMMSDR concerning the truthfulness, veracity, accuracy or legal status of any statements or opinions made and published on the IMMDSR website. Nor does the IMMSDR accept any legal liability arising from any statements or opinions so expressed and published

**WARNING: Please be aware some evidence contains descriptions, pictures and audio of the harm suffered by individuals. Some may find this distressing.**

# #MASHEDUPBYMESH

#Mashedupbymesh is a patient group that supports mesh affected individuals and was set up earlier in 2018.

This document contains summarised and anonymised information from mesh injured women. This should form part of our submission, alongside the mental health impact survey from SOS Silence of Suicide, which is attached to the same email.

Frequent Comments from mesh injured patients include:

*The extent of the physical damage caused by their mesh implants, for example, vaginal and lower abdominal pain, bleeding, back pain, leg pain, chronic infections, exhaustion and nausea.
*The impact that the physical issues have on their family life, social life and work life.
*The indifference that mesh patients are subjected to by GPs and Consultants, many of whom do not even consider the patient's mesh history and if they do, feel it's not responsible for the current problems.
*Concerns over what other physical issues could be caused by mesh and its compounds going forward. It is known that polypropylene resin contains an ingredient which can cause cancer.
*Being told that the menopause is responsible for a great many of the physical symptoms patients present with
*The lack of qualified and competent surgeons who can carry out full removals. Many surgeons appear to be pushing for partial removals, which a large majority of women are rejecting.
*That there is little, and insufficient, understanding & support of psychological harm endured by mesh affected patients.
*There are thoughts of suicide and self harm and instances of actual self harm and suicide attempts.
*Lack of confidence in the medical profession

*Women are concerned about any attempted removal surgery. It is not always possible to completely remove mesh. Therefore, are they meant to live the whole of their lives in pain and despair?
*A lady lost her womb after enduring severe bleeding after mesh implant surgery.
*Anger that mesh affected patients have been used as guinea pigs
*Anger that medical devices can so easily slip onto the market, and even more easily into their bodies
*Anger at the lack of information and transparency
*Anger that there is no mandatory recording of interest held by members of the medical profession with product manufacturers and suppliers.
*Deep sadness that some lives have been irrevocably changed for the worst.
*Disbelief that mesh has continued to be used for so long and problems reported by patients were dismissed (and continue to be so).
*Anger and sadness at the loss of life due to mesh complications.
*Worry about finances as some people have had to give up work.

**QUESTIONS:**

**Below are some questions/comments I have, some of which I should like to ask at the oral hearings:**

Were the long and short term effects of plastic mesh components implanted into the human body ever measured by the pharmaceutical companies, regulatory authorities, NHS and/or consultants?

If not, was there a requirement for this to have been done? If there wasn't, why wasn't there?

If this has been done, what were the manufacturers findings and did they share these findings with the medical profession?

How many consultants, NHS and private, have any form of interest or association whatsoever with manufacturers of mesh products? The same question for agents who sell these products on behalf of the manufacturer.

Is it known if there were more, less or no real difference in the number of patients referred for mesh implants through the NHS v Private?

How many meshes have been inserted for SUI during hysterectomy operations for prolapses?

For all mesh injured patients, there should be an automatic granting of PIP without the need for forms and appointments which absolutely cannot ascertain the level of suffering and/or need

Were any studies conducted into mesh device failure once implanted? What were these? What were the outcomes? If these studies took place, by whom were they conducted, by whom were they requested and with whom were the results shared? If no studies, why not?

If data is available, what percentage of consultants have been advising women to have mesh implants and not discussing other options that may have been available to them?

For what reason(s) did the medical profession choose to recommend the use of mesh over other, traditional methods? Did the Department of Health sanction the use of mesh? If so, what evidential data did they use prior to endorsing mesh?

Did any regulatory body, NHS, Consultant, GP ever ask how the mesh would be removed if necessary and indeed if it could be removed?

Did anyone ever study the impact upon mesh patients should device issues occur, ie, inflammation, erosion, bleeding, pain?

What steps have been taken since the vaginal prolapse mesh ban by NICE in 2017 and subsequent temporary suspension this year, to ensure surgeons are being trained to remove the implant?

Given that removing mesh 'is like trying to get chewing gum out of hair' and women are being told it isn't always possible, what happens to us? Do we have to live like this for ever? Is there research being conducted that can help alleviate some of our problems? Will the problems we face now increase and worsen as time goes on and the mesh remains in our bodies longer?

Is research being conducted into the possible wider impact(s) of plastic within our bodies?

Could member of the medical profession please explain why some women, when presenting with mesh related issues, are told symptoms are due to the menopause?

All women who've had mesh implants should be invited for regular, free, trans labial screenings on a yearly basis given that mesh complications are not always immediate and in some cases, take years to present.

Do we know how many women cannot have mesh removed because it's too difficult and/or dangerous? What other options do these women have?

Do we know how many women are still experiencing problems following a partial removal?

Do we know how many women have had:

a) More than one mesh implanted?
b) More than one partial removal?

Have any challenges been mounted to change the law in relation to the ease with which medical devices can be available for use on patients?

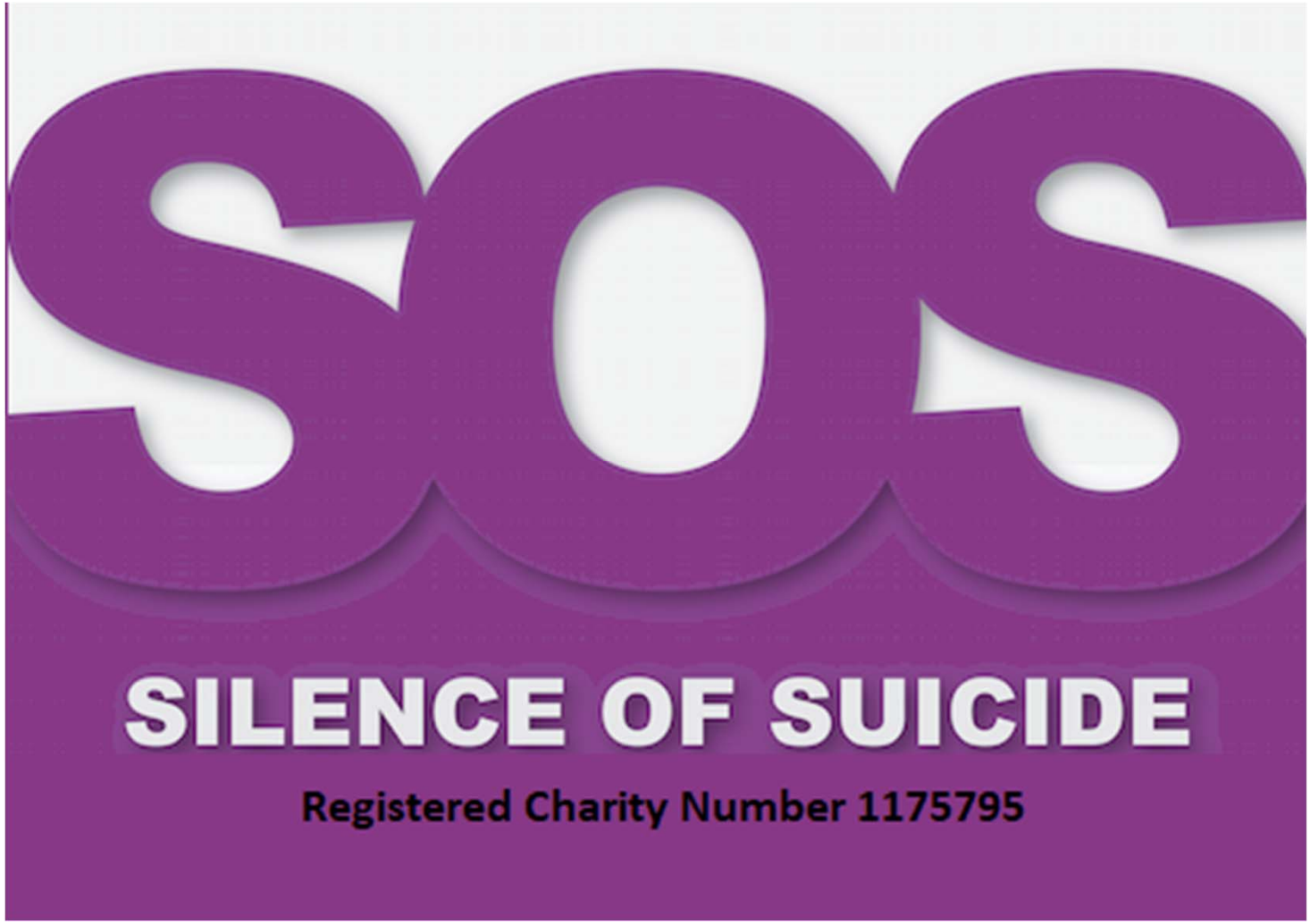
Finally, please, recommend that mesh is banned. Completely. The tragedy and loss that has visited so many individuals and their families cannot be allowed to continue.

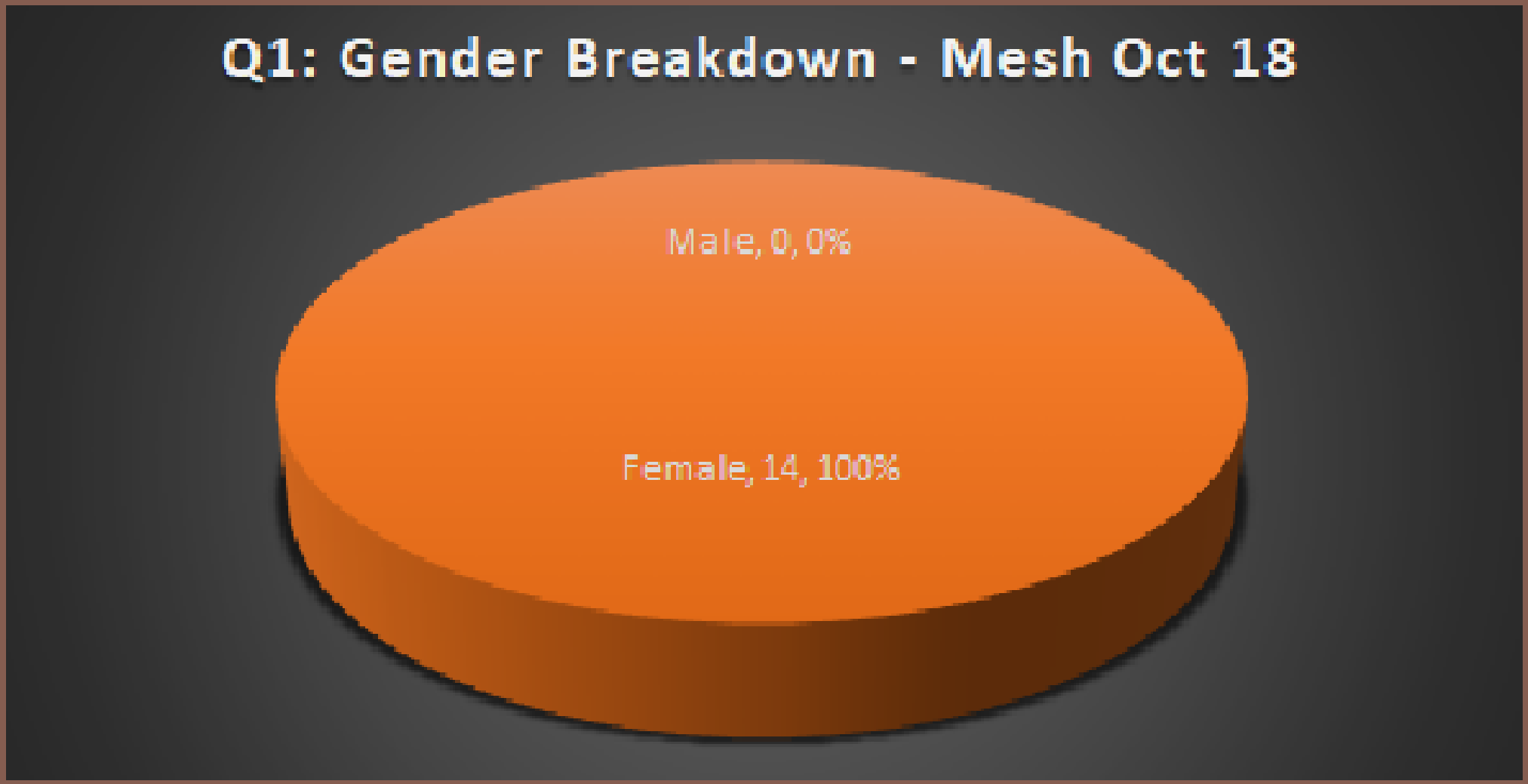
#mashedupbymesh on Facebook

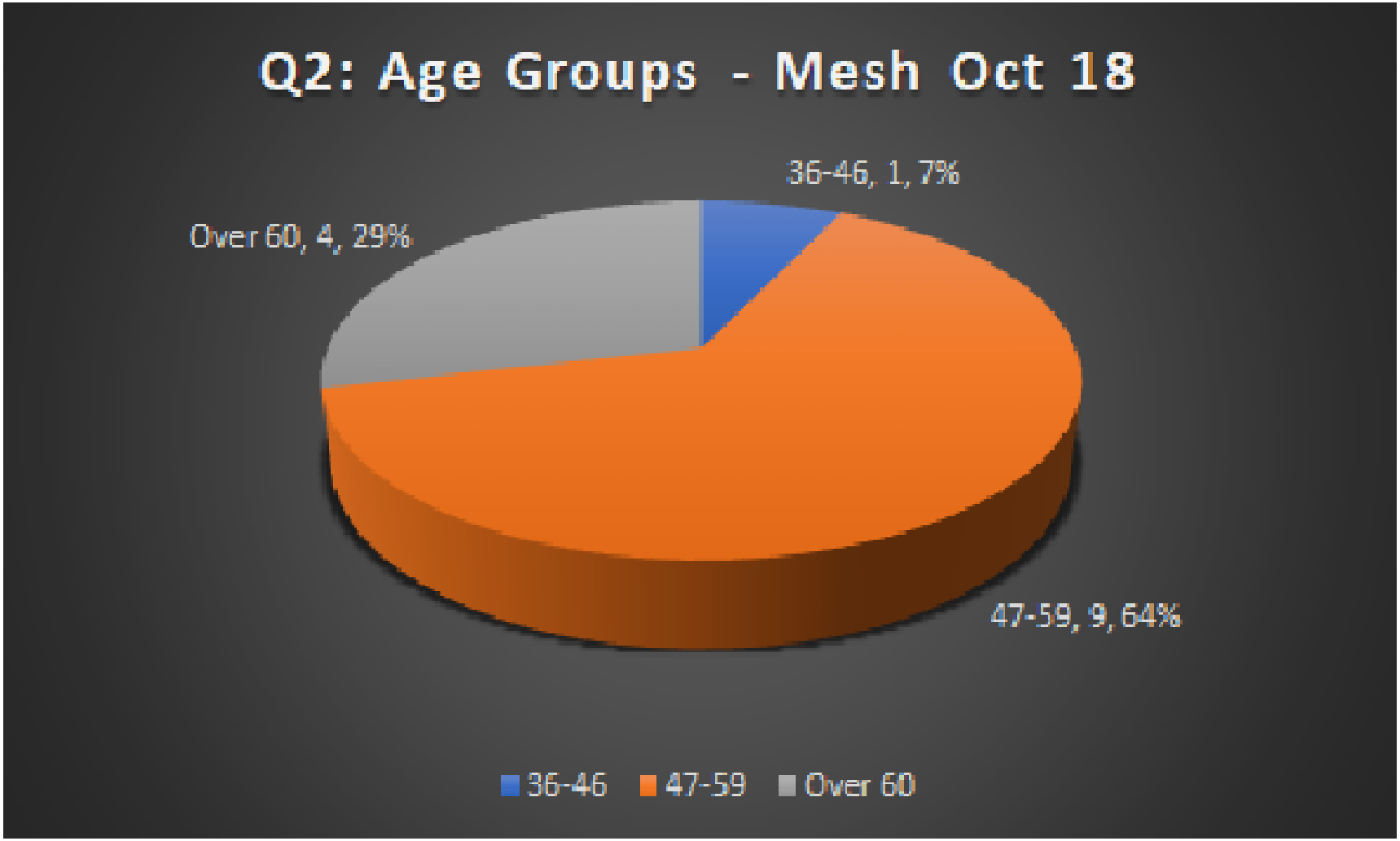
Information & support group for mesh injured individuals

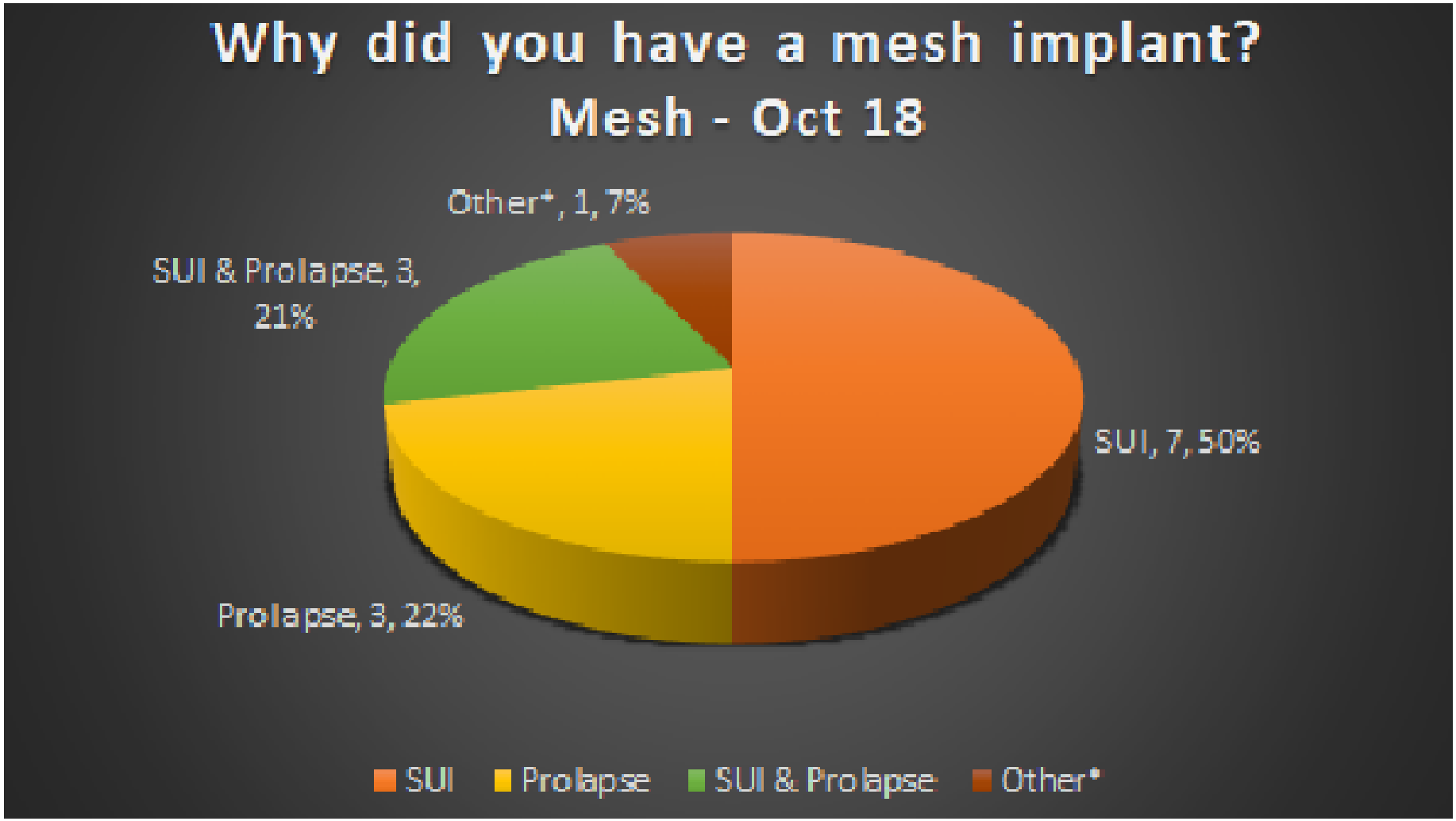
Survey and data provided by host Charity SOS Silence of Suicide at our request

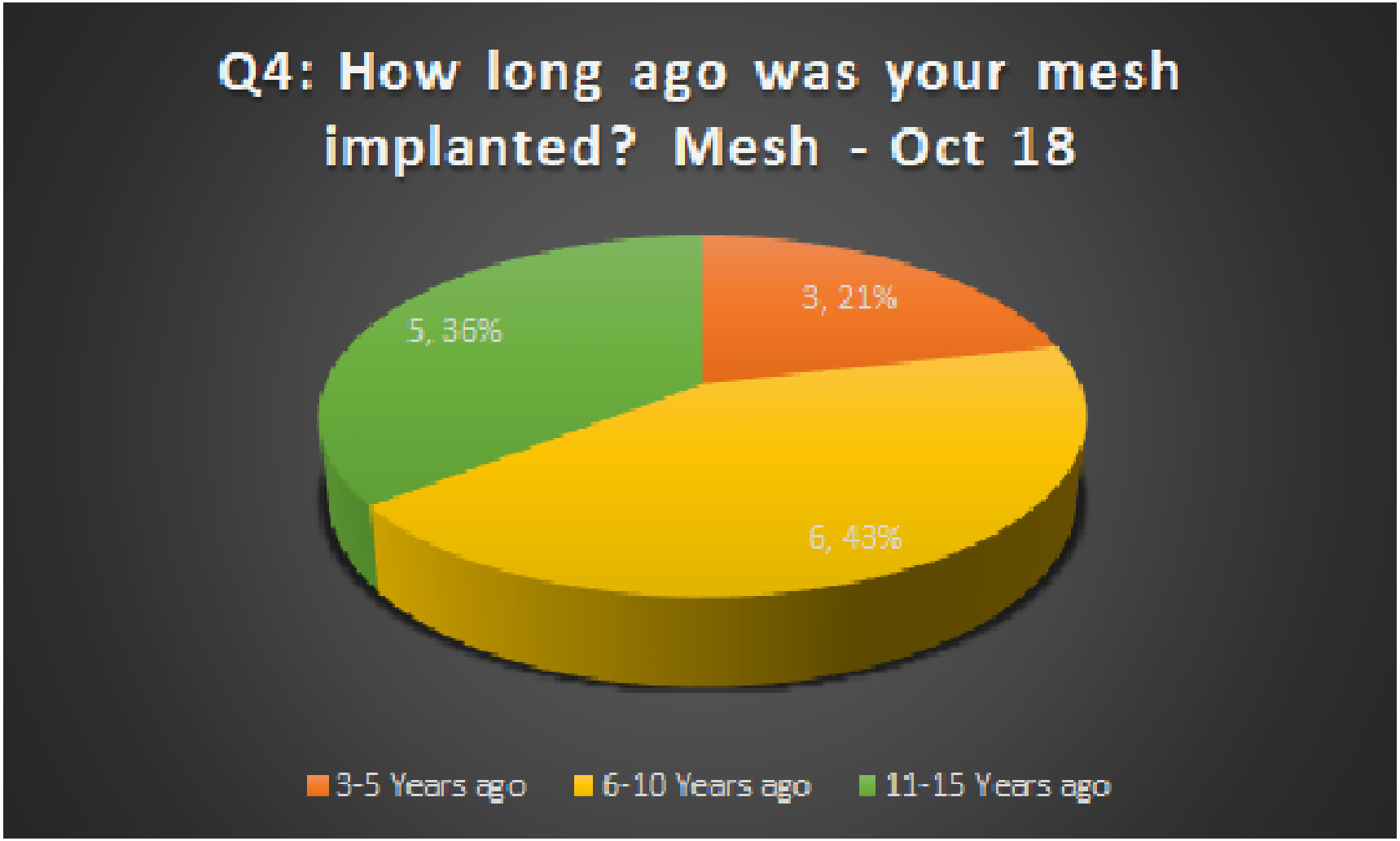
Email: [redacted]

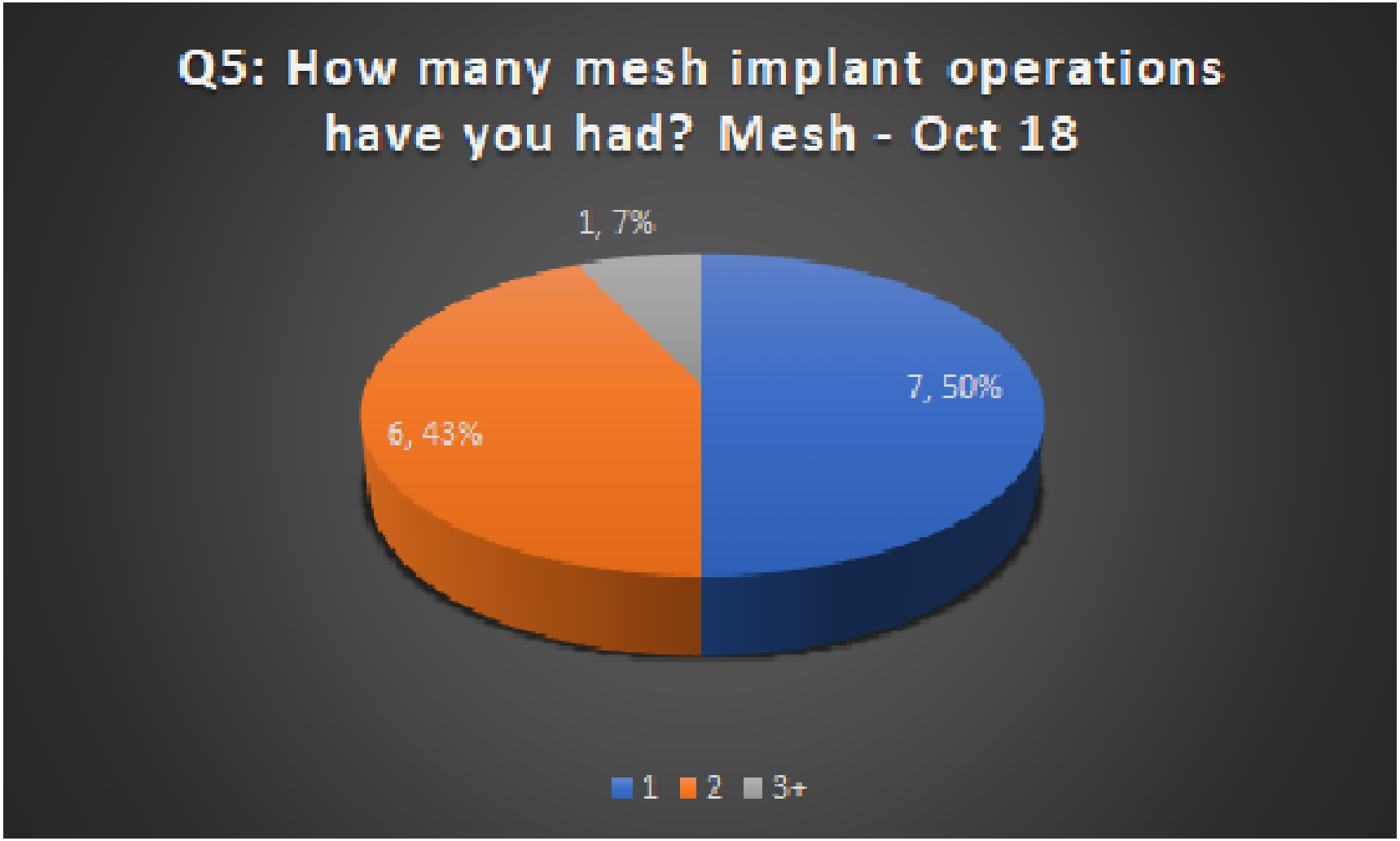

SOS
SILENCE OF SUICIDE
Registered Charity Number 1175795

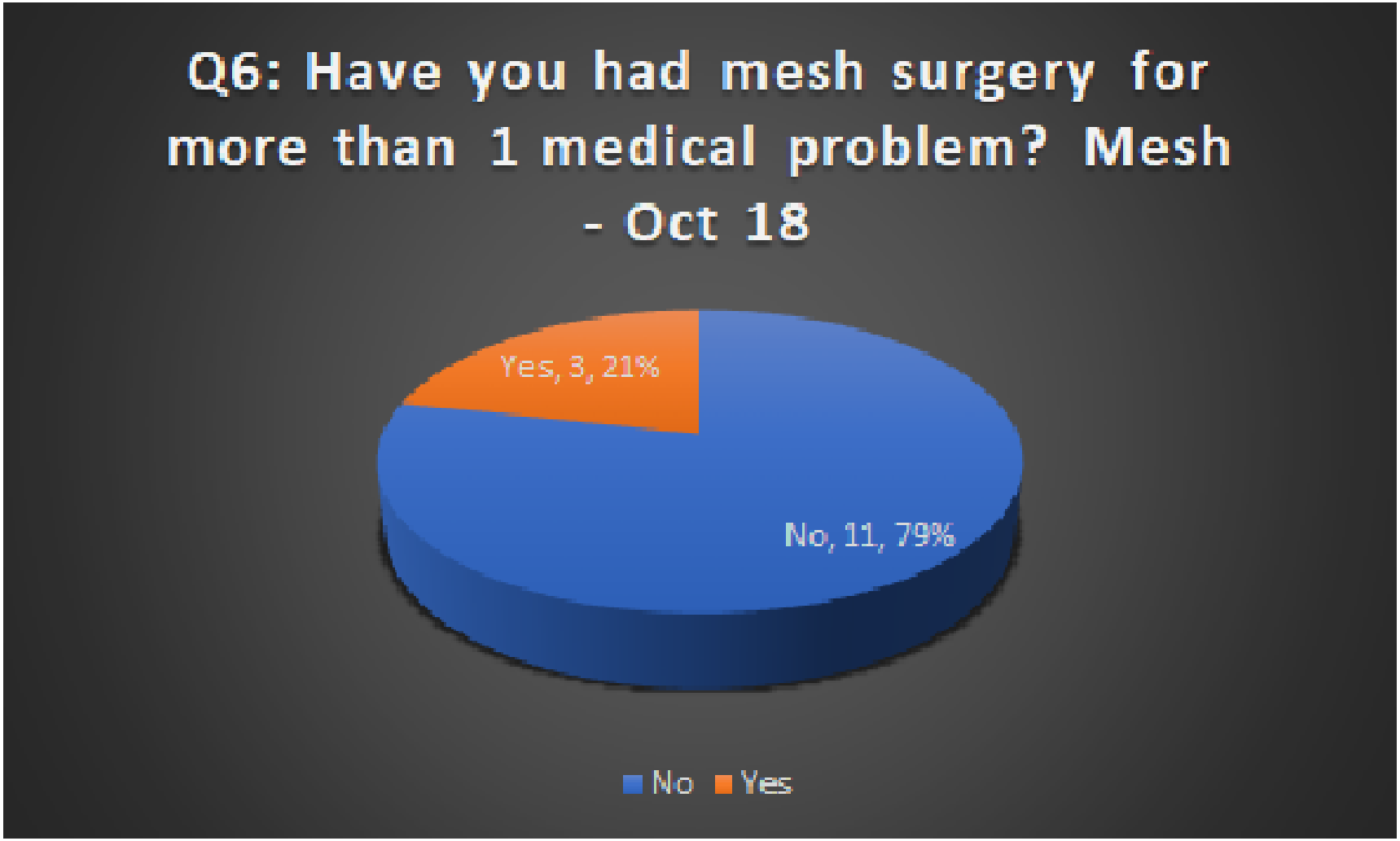

Q1: Gender Breakdown - Mesh Oct 18
Male, 0, 0%
Female, 14, 100%

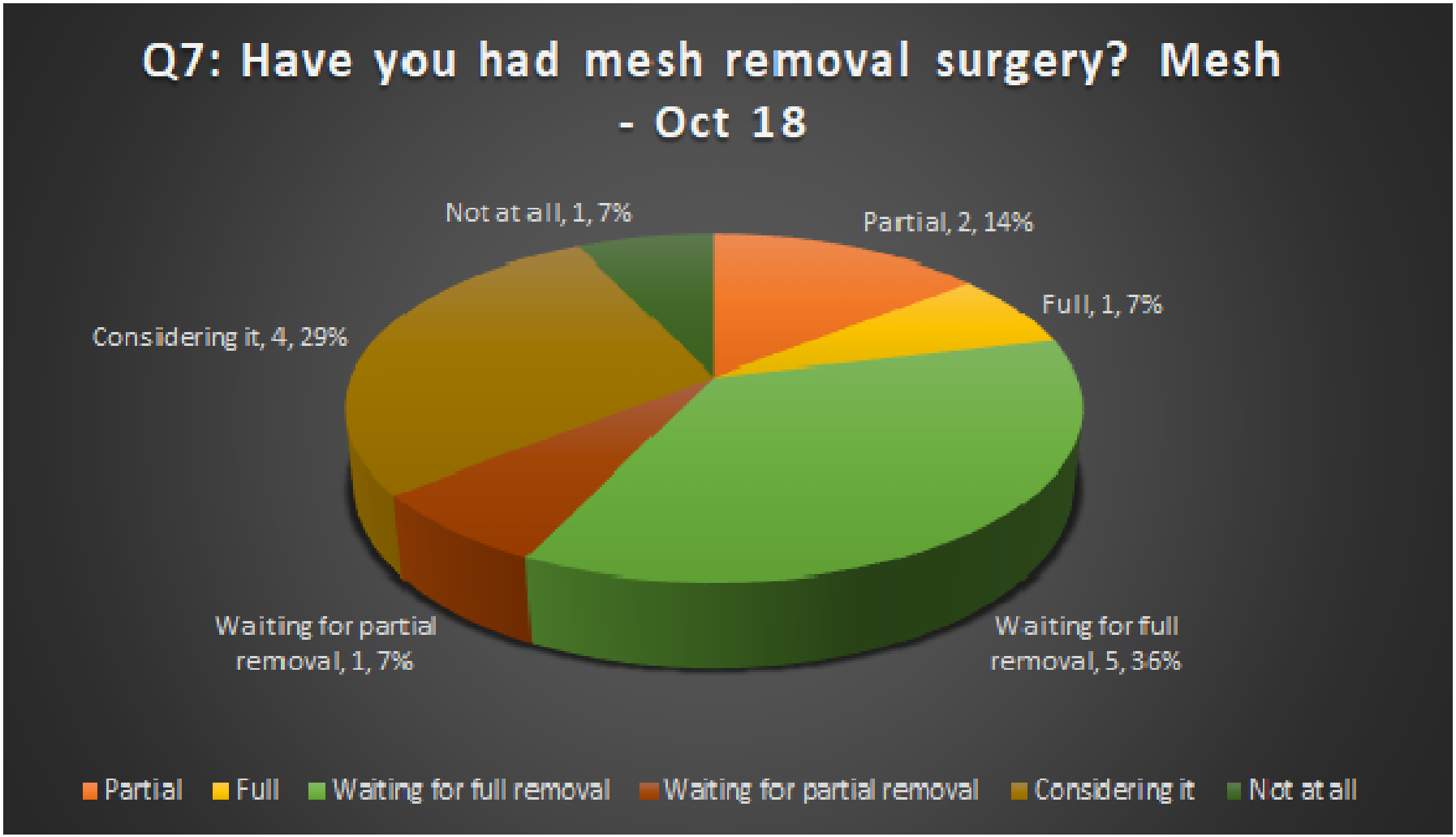

Q2: Age Groups - Mesh Oct 18
36-46, 1, 7%
Over 60, 4, 29%
47-59, 9, 64%
36-46
47-59
Over 60

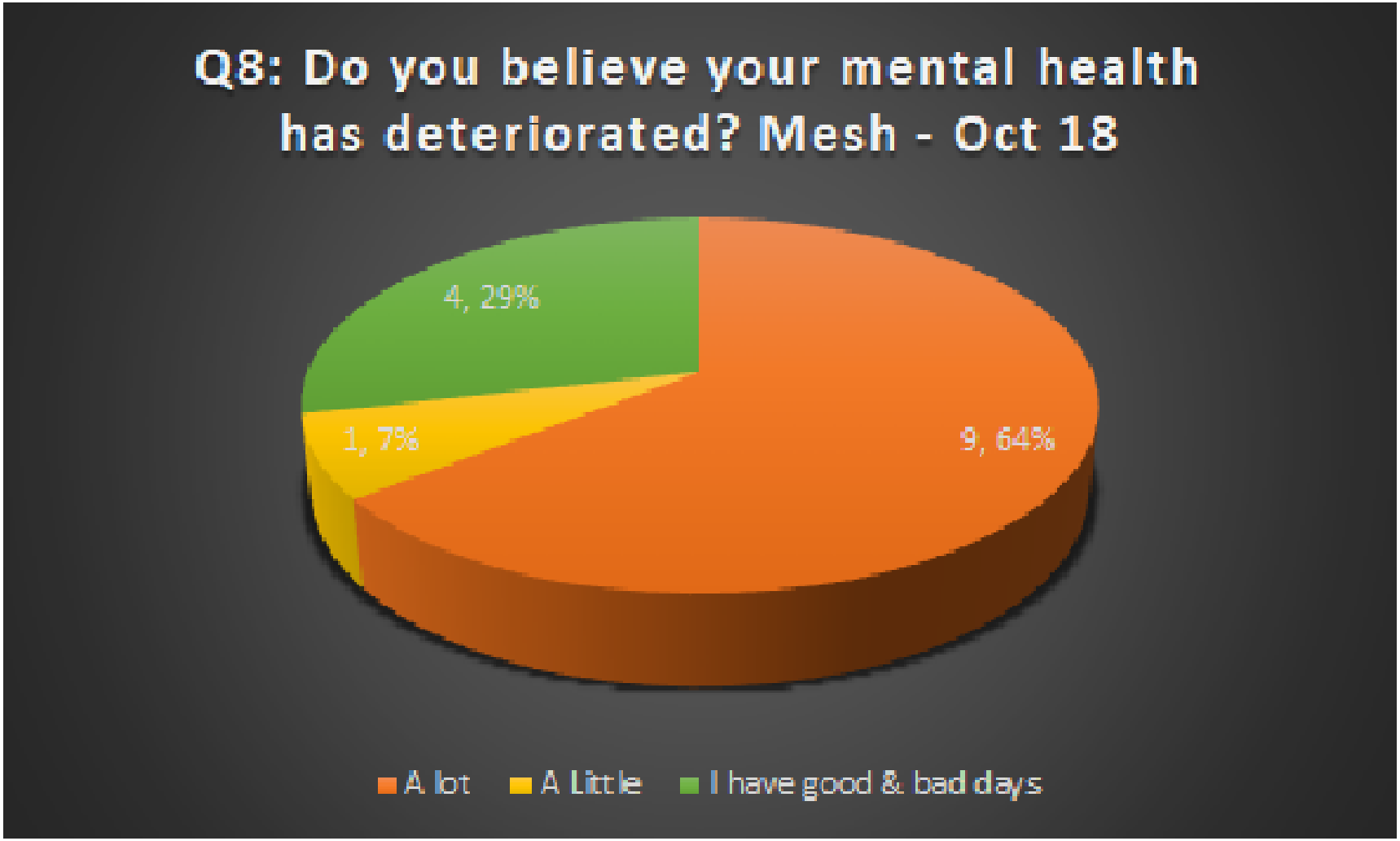

Why did you have a mesh implant?
Mesh - Oct 18
Other*, 1, 7%
SUI & Prolapse, 3, 21%
SUI, 7, 50%
Prolapse, 3, 22%
SUI
Prolapse
SUI & Prolapse
Other*

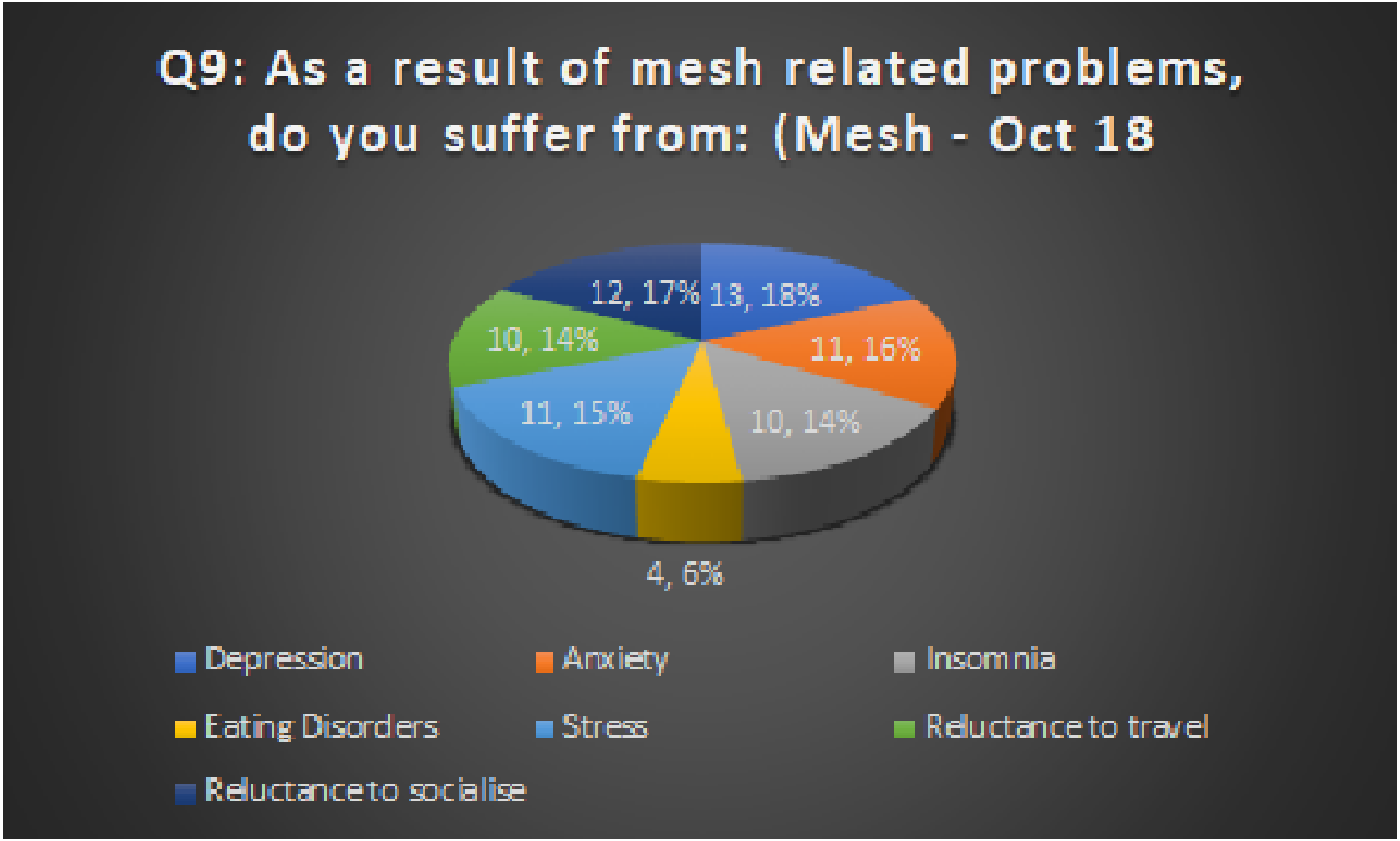

Q4: How long ago was your mesh implanted? Mesh - Oct 18
3, 21%
6, 43%
5, 36%
3-5 Years ago
6-10 Years ago
11-15 Years ago

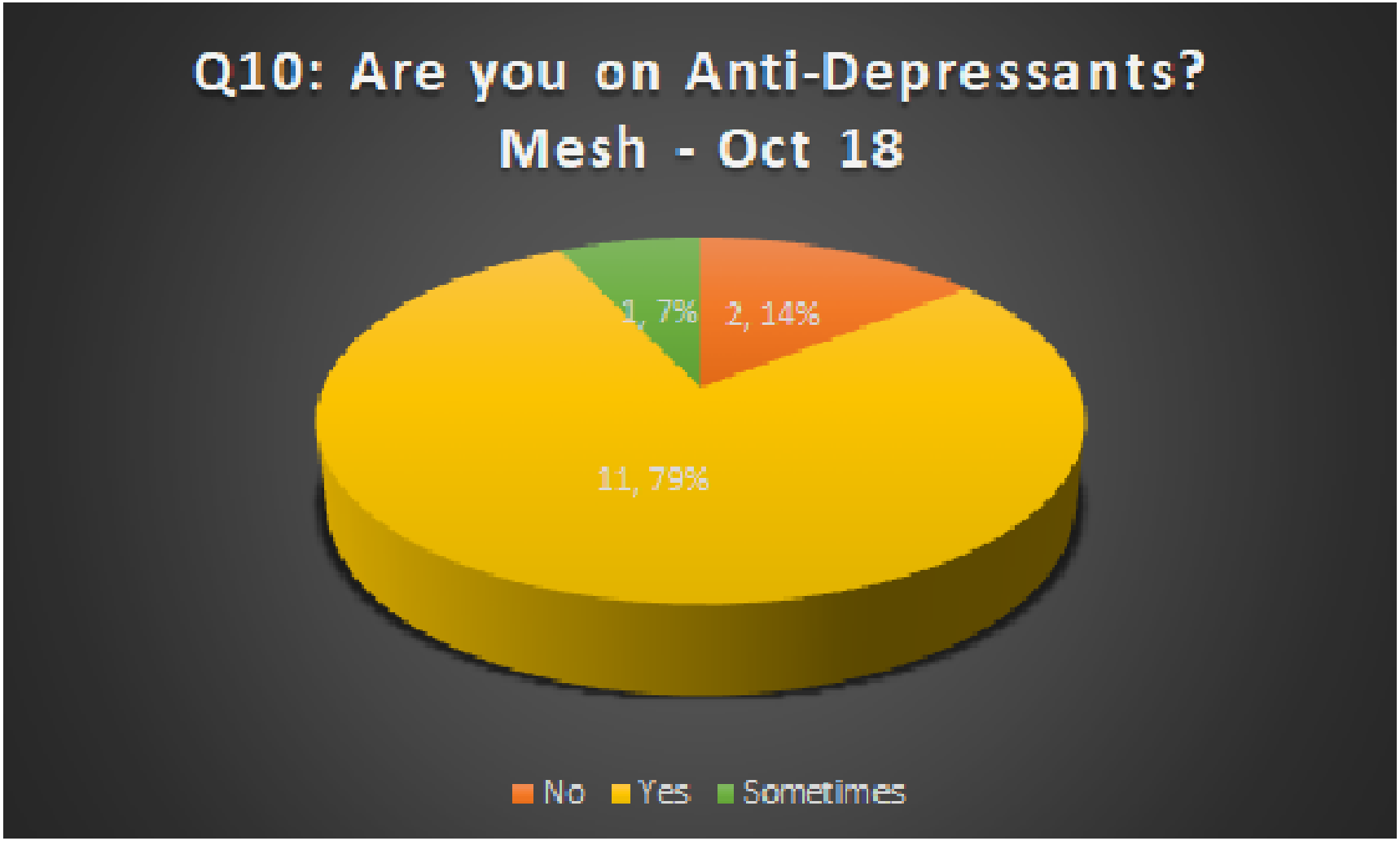

Q5: How many mesh implant operations have you had? Mesh - Oct 18
1, 7%
7, 50%
6, 43%
1
2
3+

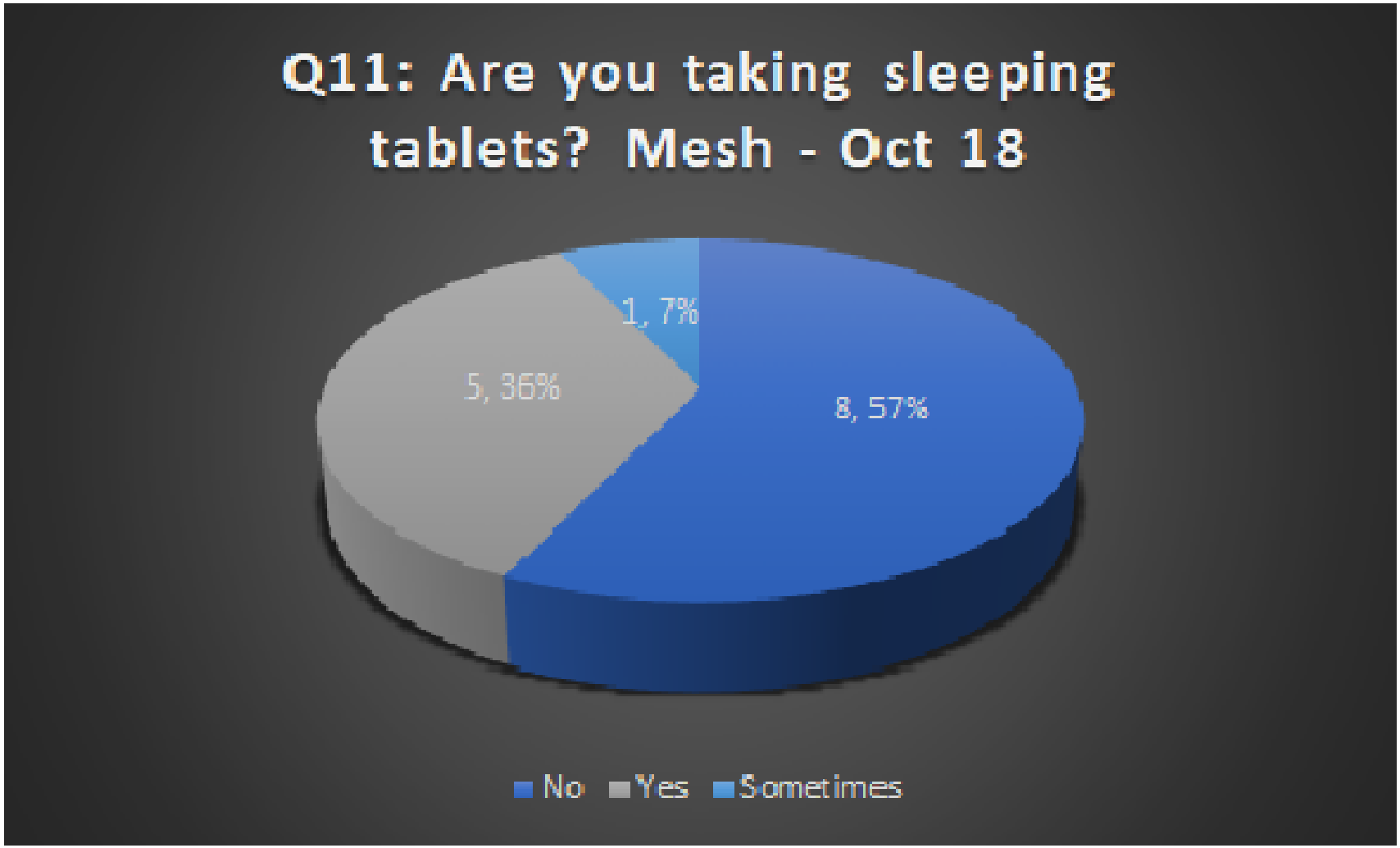

Q6: Have you had mesh surgery for more than 1 medical problem? Mesh - Oct 18
Yes, 3, 21%
No, 11, 79%
No
Yes

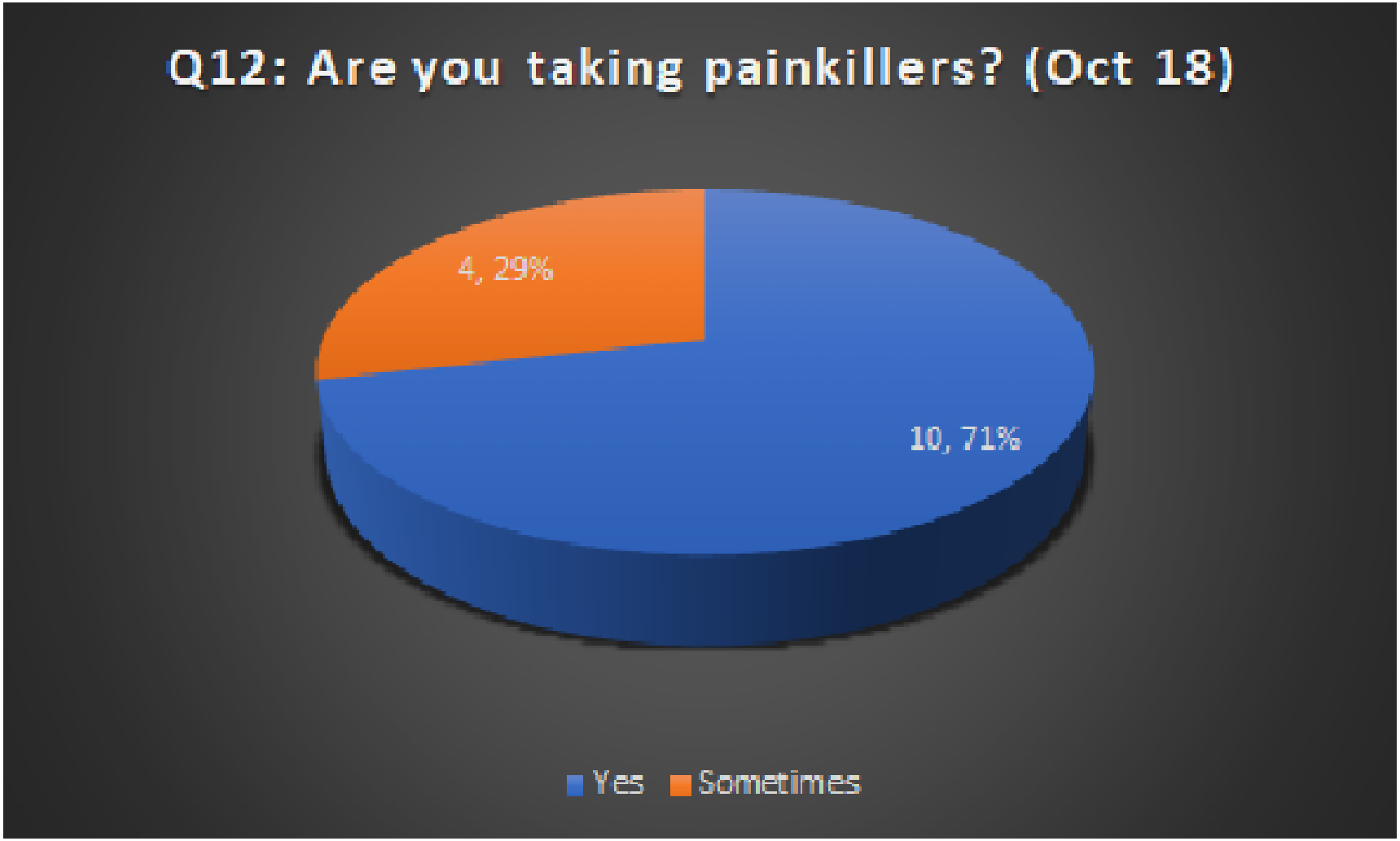

Q7: Have you had mesh removal surgery? Mesh - Oct 18
Not at all, 1, 7%
Partial, 2, 14%
Full, 1, 7%
Considering it, 4, 29%
Waiting for partial removal, 1, 7%
Waiting for full removal, 5, 36%
Partial
Full
Waiting for full removal
Waiting for partial removal
Considering it
Not at all

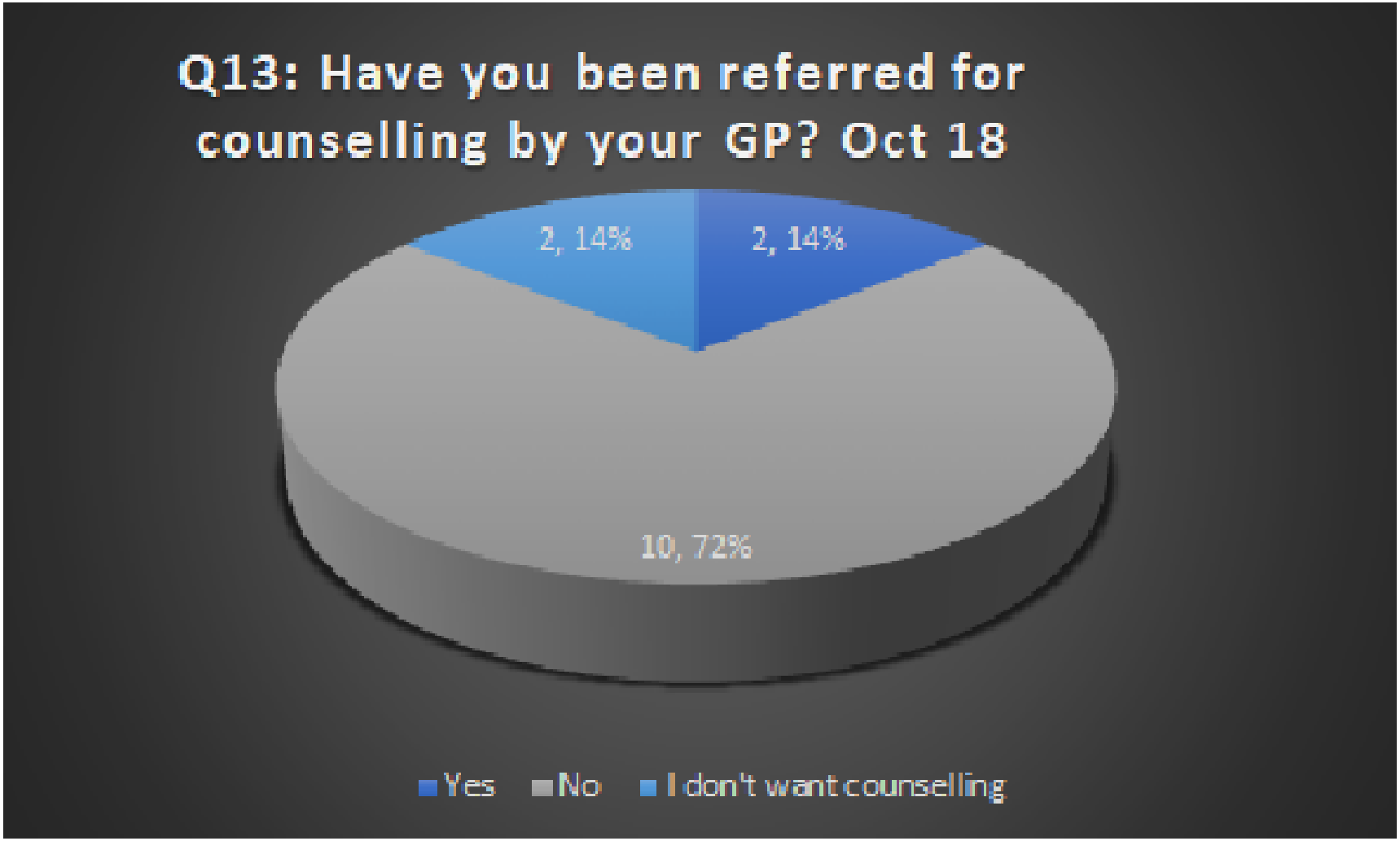

Q8: Do you believe your mental health has deteriorated? Mesh - Oct 18
4, 29%
1, 7%
9, 64%
A lot
A Little
I have good & bad days

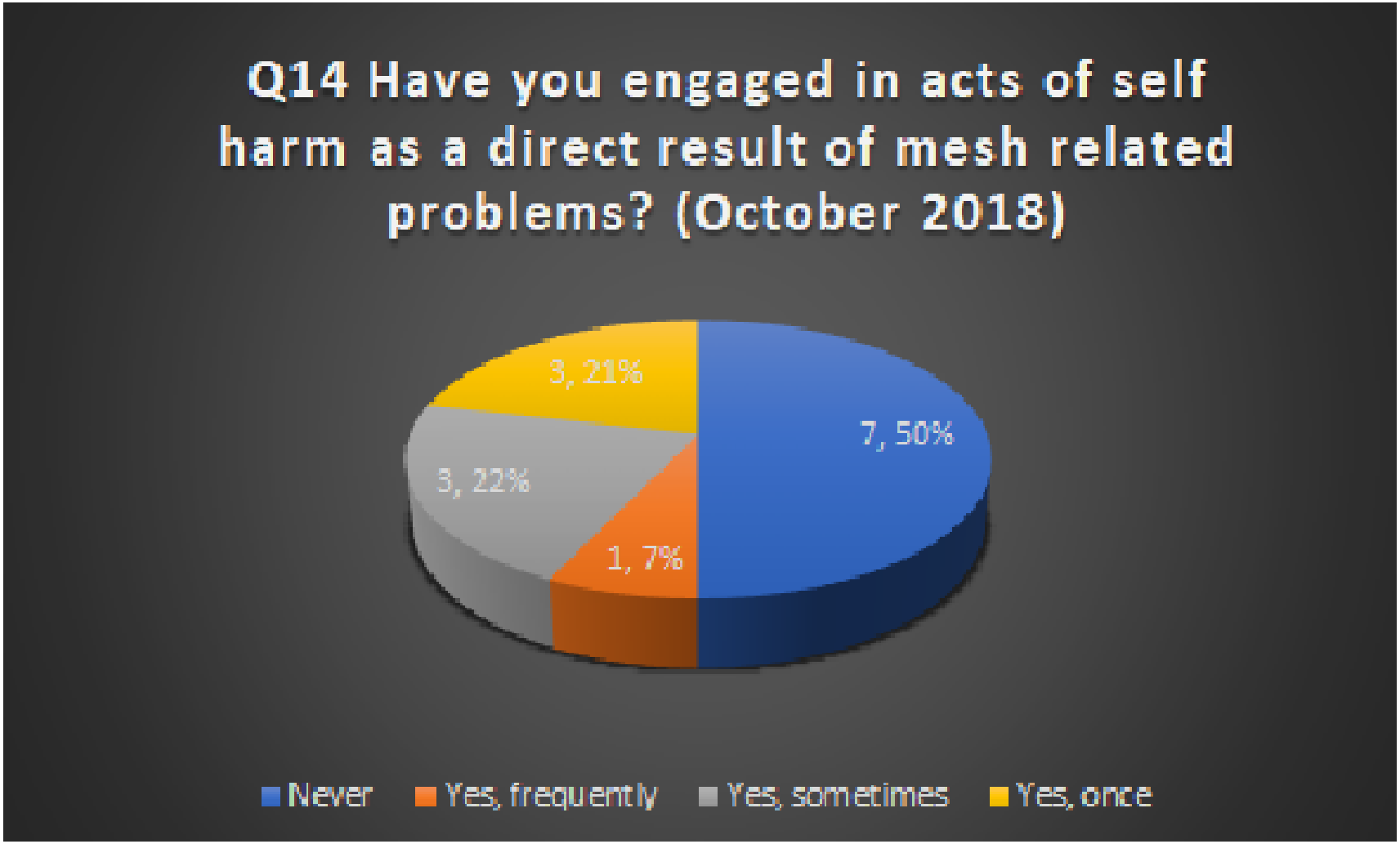

Q9: As a result of mesh related problems, do you suffer from: (Mesh - Oct 18
12, 17%
13, 18%
10, 14%
11, 16%
11, 15%
10, 14%
4, 6%
Depression
Anxiety
Insomnia
Eating Disorders
Stress
Reluctance to travel
Reluctance to socialise

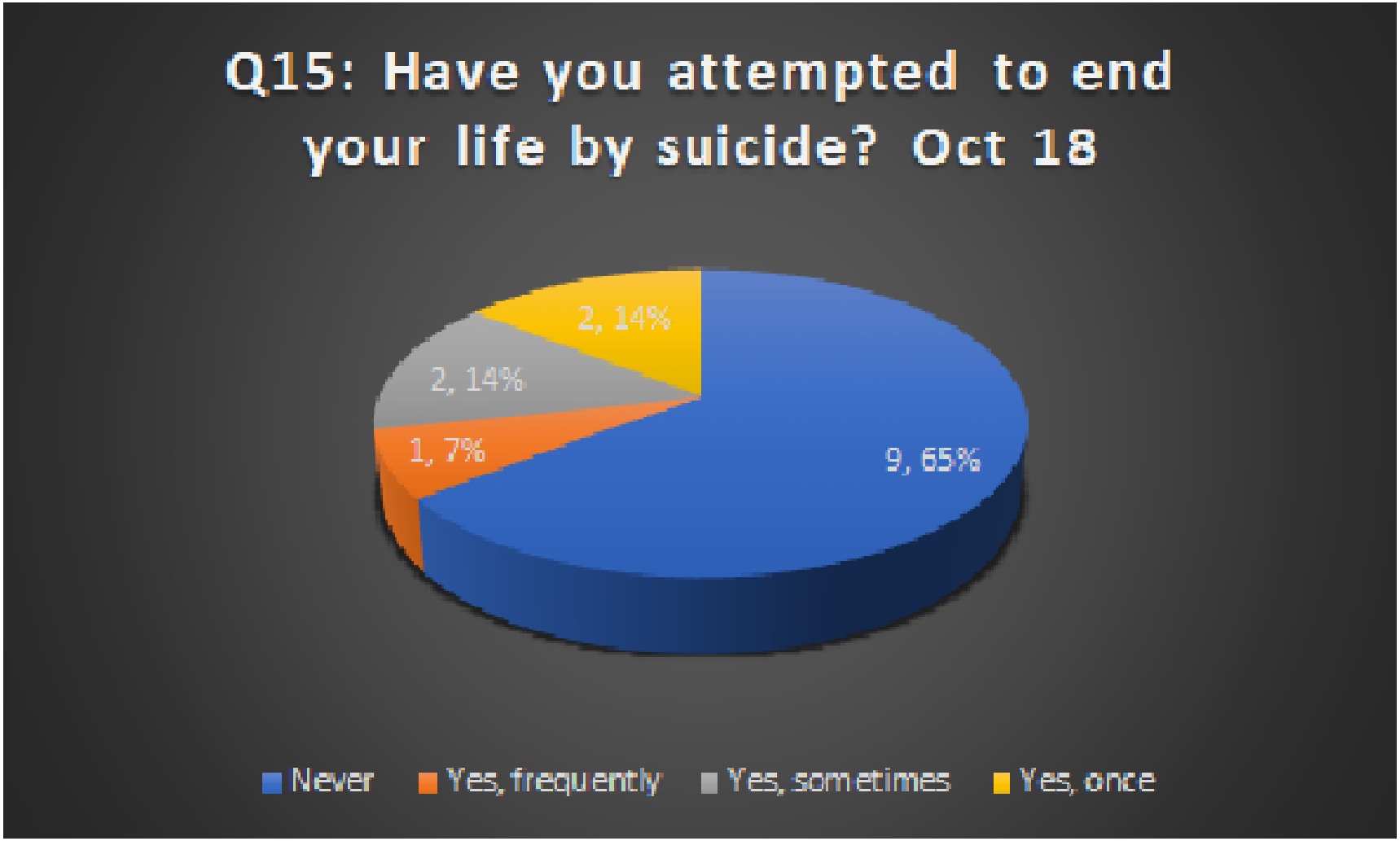

Q10: Are you on Anti-Depressants?
Mesh - Oct 18
1, 7%
2, 14%
11, 79%
No
Yes
Sometimes

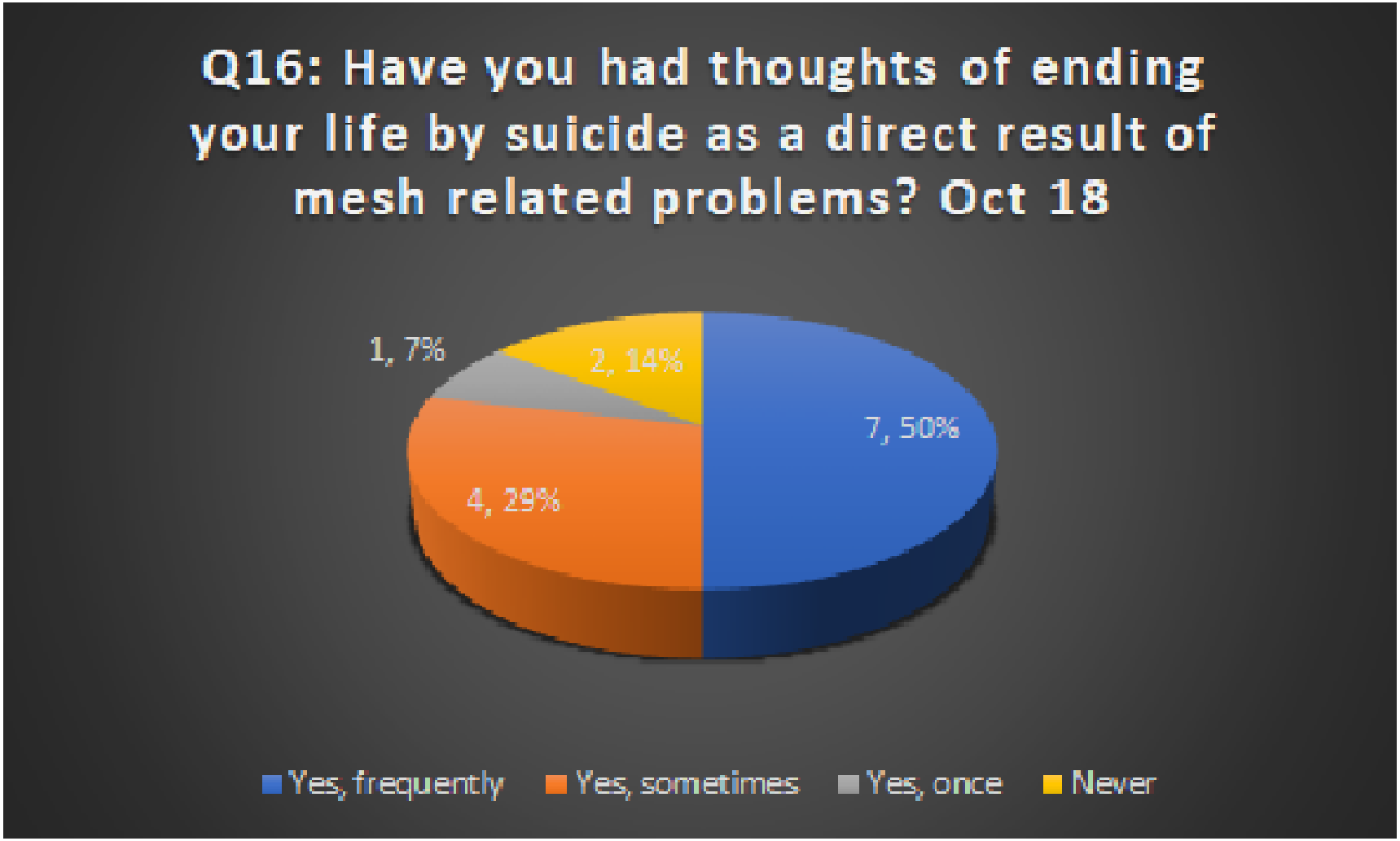

Q11: Are you taking sleeping tablets? Mesh - Oct 18
1, 7%
5, 36%
8, 57%
No
Yes
Sometimes

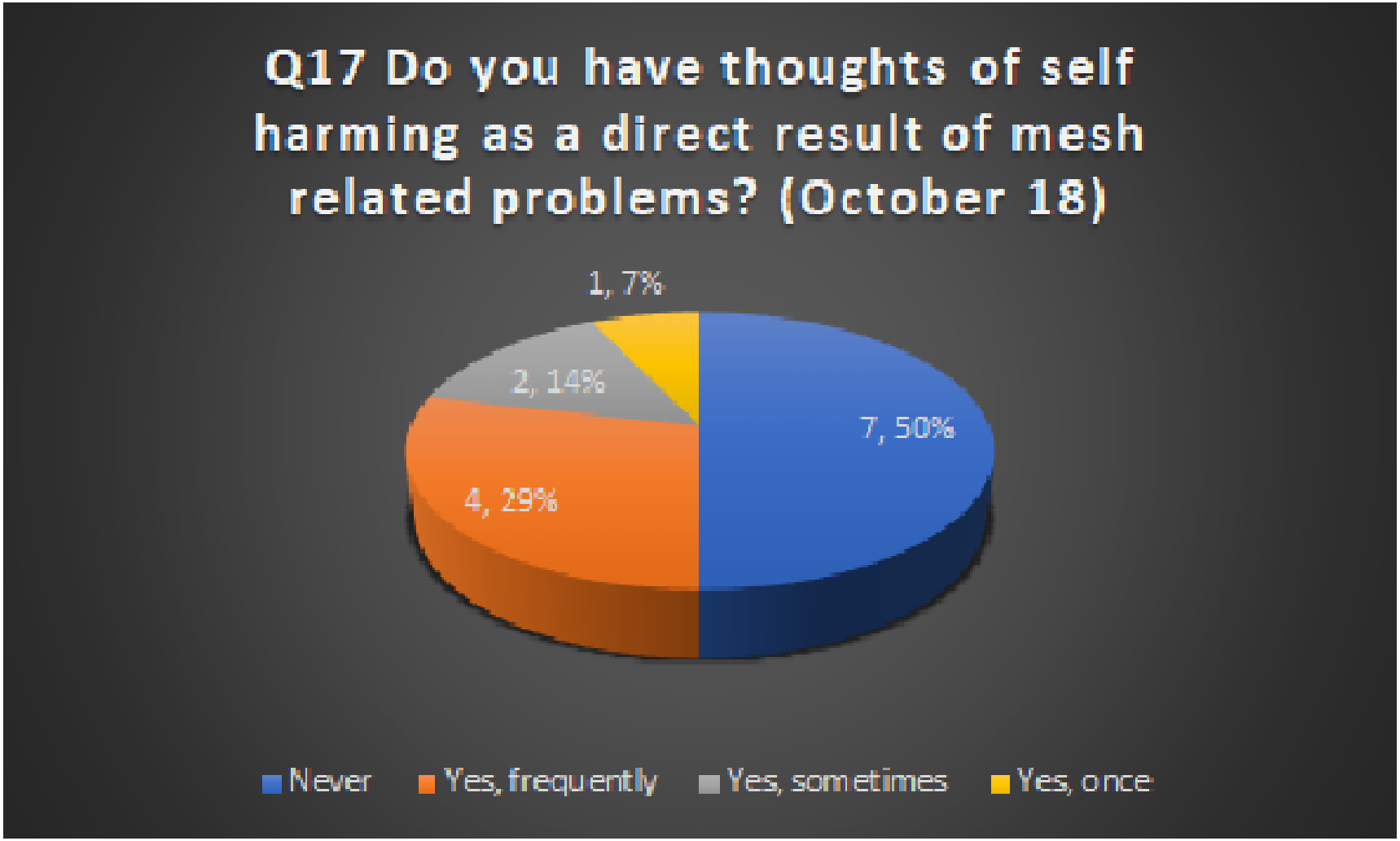

Q12: Are you taking painkillers? (Oct 18)
4, 29%
10, 71%
Yes
Sometimes

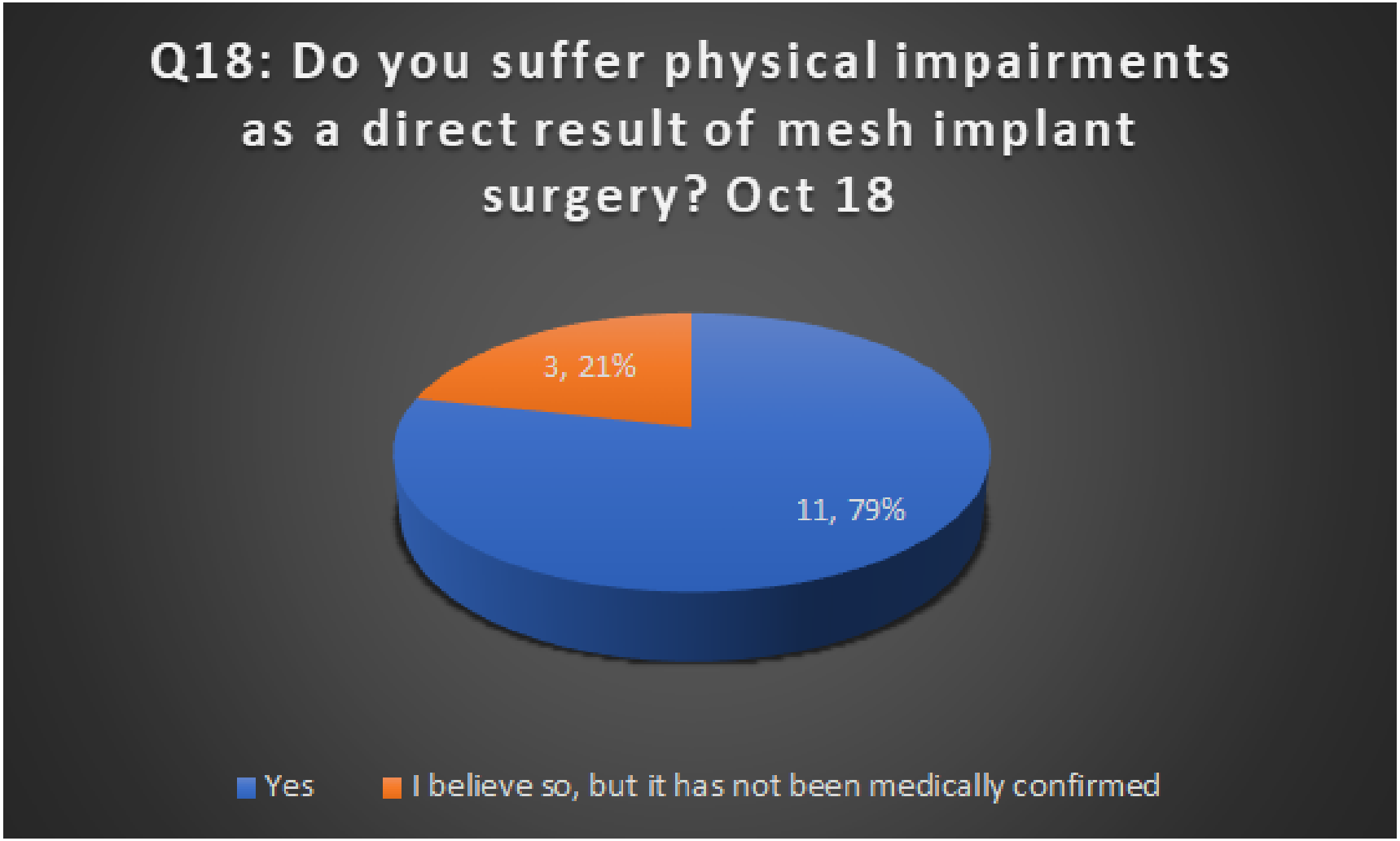

Q13: Have you been referred for counselling by your GP? Oct 18
2, 14%
2, 14%
10, 72%
Yes
No
I don't want counselling


Q14 Have you engaged in acts of self harm as a direct result of mesh related problems? (October 2018)
3, 21%
7, 50%
3, 22%
1, 7%
Never
Yes, frequently
Yes, sometimes
Yes, once


Q15: Have you attempted to end your life by suicide? Oct 18
2, 14%
2, 14%
1, 7%
9, 65%
Never
Yes, frequently
Yes, sometimes
Yes, once


Q16: Have you had thoughts of ending your life by suicide as a direct result of mesh related problems? Oct 18
1, 7%
2, 14%
7, 50%
4, 29%
Yes, frequently
Yes, sometimes
Yes, once
Never


Q17 Do you have thoughts of self harming as a direct result of mesh related problems? (October 18)
1, 7%
2, 14%
7, 50%
4, 29%
Never
Yes, frequently
Yes, sometimes
Yes, once

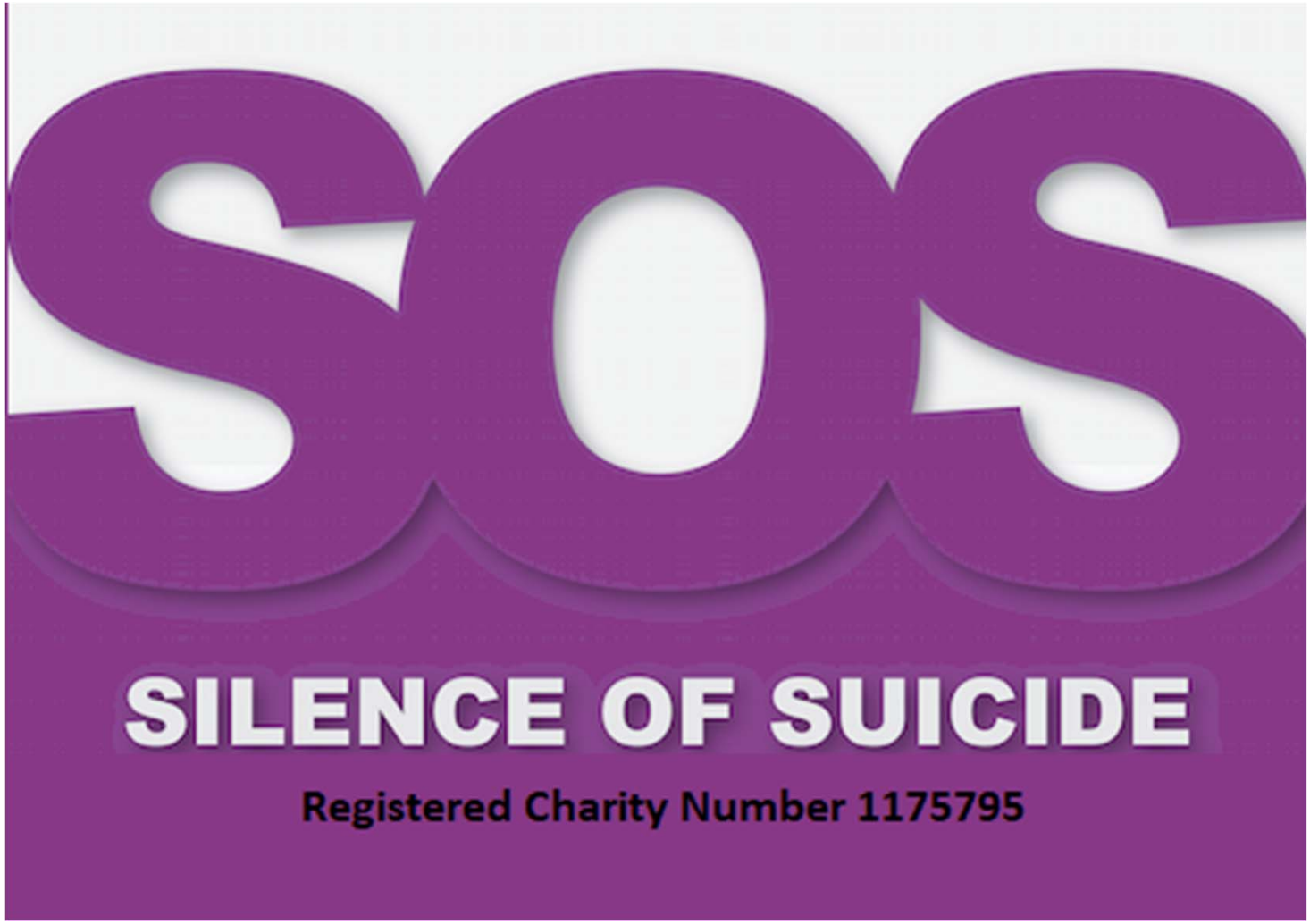

Q18: Do you suffer physical impairments as a direct result of mesh implant surgery? Oct 18
3, 21%
11, 79%
Yes
I believe so, but it has not been medically confirmed

# #MASHEDUPBYMESH MENTAL HEALTH IMPACT SURVEY ON MESH PATIENTS – OCTOBER 2018

## Hosted by SOS Silence of Suicide

## Additional Notes

1. All questions asked were in relation to the mental health impact (if any) upon mesh patients as a **direct result** of their mesh implant(s) & were worded as such. The question descriptions on the graphs attached have, in some cases, been shortened in order to fit all information in.
2. A total of 14 responses were received at the time this presentation was prepared. (24 October 2018). The graphs show the responses expressed as both percentages and numbers.
3. Question 9 allowed for multiple responses.
4. Question 3 'Why did you have a mesh implant?' is marked * to cover one answer of **"collapsed rectum, rectocele, intussusception"**
5. **All data remains the property of SOS Silence of Suicide & must not be shared or reproduced without prior written consent, which can be obtained upon request from** [redacted]
6. This survey was hosted by ourselves at the request of Patient Group #Mashedupbymesh & the anonymous results are to be shared with Independent Medicines and Medical Devices Safety Review who may use this data for evidential purposes.
7. Some answer options were never selected (eg, No) so for ease of data management, these have been excluded from the graphs


SOS
SILENCE OF SUICIDE
Registered Charity Number 1175795

# 1. Evidence submission

The following extracts from the evidence submission have been agreed for publication:

Evidence

Introduction

**We have no alternative but to raise serious and grave concerns about surgical mesh, the care received, and raise serious complaints that are truly criminal in nature.**

LAW: The Montgomery ruling
-The 2015 Montgomery ruling has practical implications for how clinicians obtain consent and support patients to make decisions about their health care. Doing something to someone without their consent is common law assault.

It is therefore criminal to implant something into a patient without a diagnosis.

When you consent as patients you are told about perforations that may happen during an operation, you don't imagine in your wildest dreams that they would use a sharp toxic plastic mesh, putting you at life-altering risks for the rest of your life. Who would consent to that level of risk for any one surgery? Imagine your surgeon doing extra surgeries to you, your life is permanently altered and there is nothing they can do to undo the atrocious barbaric torture that you endure every day for the rest of your life.

There appears to be absolutely nothing to protect patients like me who completely trusted and respected the medical profession to do what they say they would do and no more. As mesh is so widely used in the health care profession, its use is protected and therefore there is no access to justice when the product is defective. There is no reporting system enforced, or records kept, to see the magnitude of how bad this scandal is.

We have not seen any evidence that mesh is safe to be used in human tissue, it's not biocompatible. Where are the long term studies that shows what happens to mesh after years inside the human body or the impact on foetuses of unborn children with mothers who have mesh? I don't think it is acceptable to carry on implanting mesh to get the records and statistics that should have been collated before being used in humans.

It is our experience, that when implanting a toxic product such as plastic, the medical profession is not able or equipped to handle all aspects of our subsequent care. This includes the cancer issues we face, the medicines needed to help with pain (which don't work) and removal surgery to be safe and effective. Just using the word 'mesh' seems to block our access to care. It is as if there is a fear within the medical profession that the evidence would get out about how bad mesh really is, and therefore we are being left to suffer barbarically.

Having this experience, and no matter who is to blame, the manufacturers, the hospitals, surgeons or government etc., you cannot reasonably expect to carry on implanting mesh when there is really no help out there for patients when it goes wrong.

The benefits vs the risks are not feasible just for a quick operation. Ask any of the mesh injured if the benefits out way the risks and they will answer 'No!'. Are other organs being perforated by mesh an acceptable risk? If medical devices cause harm, can you help that patient afterwards and rectify the harm? What are the benefits? There are too many risks with mesh that easily out way any of the benefits.

My story is a European, but also global, story that involves 4 countries, countless medical professionals and is a story that is still continuing: -

FINAL SUMMARY

I think my story illustrates that it does not matter where in the human body this mesh is used, or even where in the world a mesh operation takes place, there is a problem with the mesh.

A medical device should not feel like you are having surgery every day of your life. It shouldn't alter you in a mechanical way or in terms of health. Just trying to walk and being sliced inside with every step significantly alters your normal daily routine and what you can do.

LAW: - Duty of candour
- Duty of candour 29th June 2015, a law passed to ensure medics tell the truth.

The fear of not doing as doctors said, is far higher than the actual harm, because we needed the help. A non-compliant patient wouldn't get the help. Nothing I have heard from any of the medical professionals or how I was being treated made any sense. I can only think that either they don't know how to help people or that they don't understand had bad this actually is. Maybe it suits them to ignore the harm. If people really knew the risks, they would not consent to this kind of surgery.

I am sick and tired of doctors inserting this product into people and then choose not to help those who are struggling with it. By now, I have met so many doctors who know the harm that mesh is causing, but they still choose to implant it. Until there is a ban, I fail to see how patients will be helped, it is much more lucrative to carry on implanting mesh than helping those that need help getting it out. I know some mesh injured victims who have had up to 14 mesh removal operations. Also, others who have been told they have had all their mesh removed, only for it to transpire that all off their mesh did not necessary mean all (100%) of it. If this product cannot be 100% removed, then it shouldn't be used.

Many of us fear going up against and confronting the medical professionals because we still need their help to get this mesh out. However, I feel they really don't understand the issues what this mesh is about, or if they do, they don't want to admit to it. Unfortunately, this will only be possible if the doctors start to address the real issue and only then will we receive real access to care, it's not enough to disbelieve patients anymore.

I have been running a public Facebook support group for the last 2 years and during this time, my admin team and I have received 26 suicide calls from mesh injured patients because they felt they could not go on with this horrendous mesh inside of them. It resonated with me the pain and suffering they were going through, and the reactions they were getting from the medical health professionals. There were times these victims where repeatedly disbelieved, lied to and made to believe it's in their head. Thankfully after talking to us, these people are still alive today.

When looking at the types of calls we were receiving, there was an approximately a 50/50 split between hernia and vaginal victims. For the hernia mesh we are getting calls from men as well as women, and It is our experience that hernia mesh is causing just as many problems as vaginal meshes.

Because of these suicide calls and through my own experiences of the medical professionals, I knew what I had to do instinctively, and that was to create a charity, Mesh UK Charitable Trust, to help those affected by mesh by offering independent support and advice, also providing respite breaks to the mesh injured and their family and carers. This came about through my own journey where I saw the impact that mesh had, not only on me, but also my family and carers.

Had I been afforded the truth no matter how ugly it really was, I could have got on with the rest of my life, and Mesh UK wouldn't have existed, and neither would this charity we established in January 2018.

I am so sorry but also very angry that this happened to me at all! I didn't have bladder or bowel incontinence, nor prolapse either! No diagnosis, no issues whatsoever! What is more upsetting is knowing that this is happening to far too many patients, globally too!

Naturally I want justice from the manufacturers, hospitals, surgeons and anyone else involved in letting this happen to me, my family but also for all other mesh victims.

The trust we have for our surgeons is far too high because we assume that, if something goes wrong, they would be able to correct it, that is not what my experience is. Through my own experiences and evidence, I trust that the Review team agree that a total ban is in order for all meshes (including Hernia mesh) because there is a problem with the product and where it is placed.

Writing this has been extremely distressing to me and my family, revisiting old recordings, videos, photographic evidence, discussing and re-awaking years of so many fears inflicted upon us.

The struggle for patients is real!

But what about the cost of mesh to the NHS and the government? While mesh may be seen as a cheap alternative to other more costly or time-consuming procedures, surely the follow-up costs must considerably out way the benefits. It stops people from being able to work and then you have all the associated costs of benefits from the DWP, social services etc to consider.
E.g. mesh could cost the government in terms of: -

- Personal Independent Payments (PIP or DLA) £320 per month
- Employment Support Allowance (ESA) £450 per month
- Doctors, consultants, surgeon appointments costs
- Ambulances
- Hospital admissions CEUR alone cost £80000 for 4wks
- Mesh removal surgery
- Medicines costs
- Care packages from social services £1000 per month

- Telecare Emergency call button
- Aids and adaptions needed in the home
- Income Tax and National Insurance contributions not being made due to not being able to work

Questions

- How can additional surgery be done to someone without presenting any symptoms, therefore being operated on without knowledge, consent or diagnosis? One can only question the surgeon's and hospital's integrity.
- Why would they deny using mesh if the product is that good?
- Why use mesh as a medical device that is not removable, especially as mesh is faulty and should never have been used in humans?
- Where has the independent testing been done to prove that mesh is fit for purpose?
- Is it ok to ruin people's lives for a leaky bladder?
- Where is the proper informed consent of using mesh, knowing ALL the risks involved with mesh? If proper informed consent was sought, nobody would agree to this surgery.
- If a proper ban was put in place, would surgeons need retraining in how to do operations without mesh? What would this cost the NHS? Therefore, maybe there won't be a ban because it would be too expensive to the NHS to retrain everyone!
- Who benefits from hospitals and surgeons using mesh, it certainly isn't the patients? Maybe it's the shareholders of the companies that manufacture mesh!
- How is it lucrative to carry on using mesh?
- Where is the protection for patients that this will not happen again it is happening all too frequently in all areas where mesh is used?
- Who is responsible for picking up the cost when this goes wrong?
- Why is there no one monitoring this, or is there someone monitoring this?

## 2. Evidence submission

**Independent Medicines and Medical Devices Safety Review**
**Surgical Polypropylene Scaffold**
On behalf of
**Mesh UK Charitable Trust**
Author – Joanne Davies
Medical Device Expert
&
Trustee

**Content**

**1. Introduction**

It is the legal duty of medical device manufacturers to ensure the safety and efficacy of their products, by providing the high level of human health protection that is to be expected by all patients; governed by all Union policies and activities (Article 168) as laid down by the Treaty on the Functioning of the European Union.

This document illustrates systemic failures and how surgical mesh implants are preventing a high level of human health protection from being achieved.

It highlights the robustness of current regulatory systems when applied in their entirety; and a solution for record retrieval on the number of implants on the market.

**2. Qualifications, Experience and Testimonials**

I'm a mechanical engineer who is considered to be an expert in the field of medical devices manufacturing, regulation and compliance. My experience covers classes I, Ila, IIb & III devices, including implantable, combination products and IVDs.

My knowledge of regulatory systems for devices encompasses more than 85 countries including Russia, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Europe, Africa and Middle East, Asia, North and South America and Asia Pacific. I began my engineering studies in 1996 and have worked in industry for the past eighteen years. I have the knowledge and experience of every Quality Assurance function within a manufacturing environment, from incoming inspection to regulatory affairs management (apart from finance).

I have communicated with every European Competent Authority, global Competent Authorities, world Embassies and European notified bodies; and my experience extends to NHS quality management systems audits and the pharmaceutical industry.

I currently maintain systems for a medical device manufacturer on a part time basis as their person responsible for regulatory compliance (REGULATION (EU) 2017/745, Article 15).

I am qualified in the core principles of lifestyle medicine, chronic disease treatment and have recently qualified as a Patient Healthcare Coach. I've researched human health alongside medical devices regulation, while working in industry for the past eighteen years. I'm a Trustee of Mesh UK Charitable Trust and have been supporting iatrogenic patients for approximately the past four years on a personal level.

www.joanned.co.uk
www.joanned.co.uk/qualifications
www.joanned.co.uk/testimonials

**3. Surgical Polypropylene Scaffold**

Surgical mesh is a Class IIb, surgically invasive, implantable medical device intended to be totally introduced into the body, as a scaffold, to reinforce human bone and tissue. It's indicated for use in many surgical procedures throughout the human anatomy and many mesh devices are manufactured using polypropylene. The mesh patient population is comprised of men, women, children and babies. There are more than three hundred surgical mesh devices on the market today and they are all substantially equivalent.

**3.1 Polypropylene**

Polypropylene is a synthetic polyolefin thermoplastic polymer, manufactured by propylene polymerisation. This polymer was first introduced to the US implantable scaffold market in the 1950s. This followed the failure of nylon mesh implants introduced in France in 1944 due to known infections and complications associated with foreign body implants.

Polypropylene may be processed by a wide range of industrial thermoplastic processing methods. In the case of polypropylene for surgical mesh it's extruded, machine knitted and cut, using an ultrasonic machine.

Polypropylene has been used for the manufacture of medical device components for many years. Its use is deemed acceptable according to general safety principles. Current post market surveillance of polypropylene components supports its safety and efficacy in applications limited to transient, short term and long term use; or, as components inside other implantable devices.

However the use of polypropylene for the manufacture of permanent surgical mesh implants is not considered safe or effective. Oxidative degradation is accelerated inside the environment of human body, tiny filaments break free and chronic disease, pain and permanent disabilities are observed in patients, preventing a high level of human health protection from being achieved.

**3.2 Medical Devices Regulation**

Surgical implants have been regulated in Europe by the Medical Devices Directive 93/42/EEC (MDD) since 1993 and is regulated by the UK Medical Device Regulations 2002.
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF

Other technical standards apply, but none of these are mandatory. There is currently a new medical devices regulation in its transitional period. It was published in the Official Journal of the European Union in May 2017. This document is focused on the 1993 and 2002 medical devices regulations currently in force and, at the time of most surgical mesh manufacture.

There are many inaccuracies in the media surrounding the interpretation of the regulations for medical devices. Many articles exist that assume how devices should be regulated; usually the way drugs are and, how there is a lack of clinical trials and testing.

Medical device regulation is constantly updated globally. Although there are slight differences in regulations and manufacturing methods, engineering and safety principles remain the same. The main differences are in the way the marketing applications are put together and processed. In Australia, Canada, the US, Gulf States, South Africa, Brazil, Russia, China, Japan,

Taiwan and throughout the European Economic Area most medical devices can be relied on to be equally safe.

Pharmaceutical regulations are constantly updated too, but the route to market is quite different. Drugs have unpredictable effects on the human body and until they are tested, we cannot understand what may happen. This is completely the opposite to medical devices engineering and for all the right reasons.

Engineers are able to predict exactly what will happen using engineering mathematics, physics, chemistry, mechanical engineering science, finite element analysis, computer aided engineering and computer aided design etc.

Adequate device testing exists for every medical device that's manufactured according to applicable regulations. If we build a wheelchair for example, which is a device intended to transport a patient from A to B, we don't perform a clinical trial to see if it works. Engineers already know it will transport a patient from A to B, how strong the wheelchair will be and that it will work once it's left the 'drawing board.' We know what size it will be; the Mohr's hardness of the tyres; how long they will last; how many pounds per square inch of air those tyres can tolerate; and we even how many times the wheels will turn before they fail. But engineers go above and beyond this for safety reasons, to prove our predictions were in fact correct.

Once the wheelchair is built it will undergo different types of testing. This includes, but isn't limited to drop tests from a height, destructive testing to illustrate at what BAR/psi the pneumatic tyres explode, tensile tests, freeze tests and more.

So how do we ensure materials used in the manufacture of medical devices are safe?

Engineers test materials on animals but we don't expect human based results! We do this because we have to do it, to legally market devices in certain countries. The device type, including the duration of use and human contact, determines the degree of materials testing required. Nonmandatory standards such as 10993 (a series of technical standards for evaluating the biocompatibility of materials used in the manufacture of medical devices) are commonly applied as the generally accepted state of the art for biocompatibility.

Given the effects manufacturing and processing may have on polymers incorporated into medical devices, the use of these standards and animal testing isn't sufficient to identify the potential biocompatibility risks associated with permanent surgical implants. Although these tests for sensitivity, irritation and cytotoxicity are state of the art, there is no accounting for biological hazards that arise from mechanical failure such as oxidation degradation in vivo.

Additionally engineers may predict how materials will react inside the human body using computer aided design software for biophysical modelling research (ER 7.1). This software allows relevant anatomical models and devices to be built and simulated in a 3D environment. These are analysed to calculate the mechanical behaviour of the device in vivo and its effects on surrounding human tissue.

But to begin with, manufacturers need to know what materials they are using to manufacture their devices. Although when most materials arrive, they are labelled but we cannot know what the material is unless they are tested for material composition. For example, if one of my clients has ordered Stainless Steel 305, I ask the manufacturer how they have verified it is

Stainless Steel 305 and would need to see the relevant documented evidence, including traceability for verification.

3.3 CE Marketing Applications

CE marketing applications for surgical mesh may follow one of the applicable routes in the MDD, dependent on device classification. Device classification is determined around the vulnerability of the human body. The route chosen ensures the correct levels of manufacturing controls are applied according to risk. Any chosen route, if applied correctly, in its entirety, will verify device safety, efficacy and enable manufacturers to market their devices safely throughout the European Economic Area and the rest of the world via various marketing application processes.

There are many significant records required for every medical device that's manufactured. These shall be maintained by the manufacturer of devices including but not limited to appropriate testing, bioburden counts, sterilisation validation, packaging validation, clinical evaluation report, classification rationale and a biocompatibility report etc.

A CE marketing application is a summary of all the manufacturer's technical documentation. This summary is reviewed for completeness with the MDD's by the Competent Authority's (CAs) designates; notified bodies (NBs), for certain classes of devices, to allow the manufacturer to correctly affix a CE marking to their product (MDD Article 17).

In any CE marketing application it is critical that all applicable essential requirements are fulfilled or justified. An Essential Requirements Checklist (ERC) is submitted by the manufacturer as part of the technical documentation requirements for the review. Although the ERC isn't a requirement of the MDD, it is a useful marketing tool that illustrates the fulfilment of all applicable Essential Requirements to various economic operators throughout the supply chain.

The following table represents an abbreviated ERC and illustrates why the CE marking on surgical mesh is incorrectly affixed as all applicable Essential Requirements have to be fulfilled ad they aren't. Justifications have been omitted for Essential Requirements non applicable to surgical mesh for simplicity.

3.4

Abbreviated Essential Requirements Checklist 93/42/EEC

Polypropylene Surgical Scaffold

**P/F = PASS/FAIL**

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| GENERAL REQUIREMENTS | | | |
| 1 | The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks | When used under the conditions and for the purposes intended, devices are compromising the clinical condition and safety of patients by causing unavoidable risk and unacceptable harm, including well known foreign body reactions, calcification, sepsis, PTSD, fibromyalgia, lupus, erosion, fistula, | F |

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| | when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.<br><br>This shall include:<br><br>reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and<br><br>consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). | Sjogren's Syndrome and other chronic, mesh related illness, pain, permanent disabilities and even death.<br><br>Mesh has filaments (not visible with the naked eye) that break off and move throughout the human body, making it impossible to fully remove all elements of the devices; causing further serious harm to patients that includes exit points for filaments that have broken away from the device.<br><br>Human tissue grows around the device and scar tissue forms after initial surgery that causes more harm to the patient if removal is attempted.<br><br>Where death is an uncontrolled, unavoidable and unpredictable outcome, it does not constitute acceptable risk when weighed against any condition where death wasn't to be expected.<br>The devices are not compatible with the high level of protection of health and safety to be expected and that consumers are entitled to expect.<br><br>Risk error due to ergonomic features of the device and the environment in which the device is intended to be used is not applicable.<br><br>Consideration of the technical knowledge, experience, education and training of the user have been taken in to account for the design.<br><br>User medical and physical conditions are not applicable as the device is intended to be used by appropriately trained healthcare professionals. | |
| 2 | The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.<br>In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:<br><br>eliminate or reduce risks as far as possible (inherently safe design and construction),<br><br>where appropriate take adequate protection | Solutions adopted by the manufacturer for the design and construction of the device, don't conform to safety principles taking into account generally acknowledged state of the art.<br><br>Risks are not eliminated or reduced as far as possible and the design and construction isn't inherently safe.<br><br>There are no adequate protection measures as some harms are | F |

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| | measures including alarms if necessary, in relation to risks that cannot be eliminated,<br><br>inform users of the residual risks due to any shortcomings of the protection measures adopted. | unavoidable, unpredictable, unknown and not to be expected according to the intended use. Alarms aren't a possibility for risks that cannot be eliminated due to the device type and there is no way for patients to avoid harm.<br><br>Due to shortcomings of protection measures adopted, unacceptable, unpredictable and unavoidable risk is communicated to users via the information supplied by the manufacturer, rather than the residual risk laid down by the regulations. | |
| 3 | The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer. | Device does not achieve performance intended by the manufacturer in many cases and is not suitable for the function specified by the manufacturer as the devices achieve uncontrolled, unintended, unavoidable and unpredictable detrimental physical, physiological and psychological harm to patients. | F |
| 4 | The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. | The clinical condition and safety of patients is compromised due to the materials used that cause unintended, unacceptable and irreversible harm during the lifetime of the device when the device is subjected to normal conditions of use and the stresses that occur in the environment within the human body<br><br>There is no lifetime of the device indicated by the manufacturer as the device is intended to be a permanent implant | F |
| 5 | The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer. | The devices are designed, manufactured and packed in such a way that their characteristics and intended performance under normal use aren't adversely affected during transport and storage, taking account of the instructions and information provided by the manufacturer. | P |
| 6 | Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended. | Death, PTSD, permanent disability, depression, chronic pain, inflammation, fibromyalgia, sepsis and other chronic complications do not constitute acceptable risks v benefits of the intended performance of surgical scaffold | F |
| 6a | Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X. | Polypropylene scaffold doesn't adequately demonstrate conformity with relevant Essential Requirements and | F |

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| | | current post market surveillance illustrates the clinical performance and safety of the device cannot be claimed to be established, effective, or consistently produce the performance intended by the manufacturer in relation to its medical purpose. | |
| II | REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION | | |
| 7 | Chemical, physical and biological properties | | |
| 7.1 | The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to:<br><br>the choice of materials used, particularly as regards toxicity and,<br><br>the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device, where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand. | The characteristics and performances in Section I on 'general requirements' cannot be guaranteed as in vivo oxidative degradation, including embrittlement, shrinkage and hardening that causes unpredictable, unknown and unavoidable harm due to the toxic nature of the polypropylene material.<br><br>Material used is not biocompatible and toxic reactions are experienced by patients. Polypropylene is not considered compatible with biological tissues, cells and body fluids<br><br>Unable to locate biophysical modelling research data for polypropylene scaffold with relevant anatomical simulation. It is doubtful whether the manufacturer holds such data as via this method it is possible to simulate, analyse and predict the mechanical behaviour of surgical mesh implants in vivo, including its effects on surrounding human tissue | F |
| 7.2 | The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure. | There are no risks associated with contaminants or residues posed to the persons involved in transport, storage and use of the devices, associated with contaminants or residues | P |
| 7.3 | The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use. | The device is not intended to be used in contact with any substances or gases and is not intended to administer medicinal products<br><br>The devices are in contact with biological tissues, cells and fluids that cause harm to patients during normal use and the performance is not maintained in accordance with the manufacturer's intended use | F |
| 7.4 | Where a device incorporates, as an integral part, a substance which, if used separately, may be | The device does not contain any medicinal products | P |

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| | considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. | | |
| | For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (1) on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. | NA | |
| | Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. | The device does not incorporate any human blood derivatives | |
| | Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the | There are no ancillary substances incorporated into the device | |

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| | addition of the substance in the medical device.<br><br>When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure. | <br><br>NA | |
| 7.5 | The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (1).<br><br>If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.<br><br>If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures. | There are no risks posed by substances leaking from the device.<br><br>No part of the device is intended to administer medicines<br><br>NA | P |
| 7.6 | Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in | Risk, posed by the unintentional ingress of substances is reduced as far as possible by design and is designed so that if substances do unintentionally enter the device, it can be discarded. | P |

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| | which it is intended to be used. | | |
| 8 | Infection and microbial contamination | | |
| 8.1. | The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use | Risk is reduced as far as possible by way of manufacturing processes to eliminate or reduce the risk of infection to the patient, user and third parties using validated sterilisation methods.<br>Irregularities of the PP device design promote bacterial adherence in the environment in which the device is intended to be used.<br>The design allows easy handling but contamination of the device by the patient and vice versa isn't minimised due to irregularities of the device design that promotes bacterial adherence in vivo during use | F |
| 8.2. | Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.<br><br>Notified bodies shall retain information on the geographical origin of the animals.<br><br>Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process. | It is unknown whether the manufacturing process for polypropylene mesh incorporates tissues of animal origin, although this is highly likely as slip agents derived from animals are commonly used for polymerisation in industry.<br><br>It is not known whether notified bodies retain or request geographical information on origin of animals if the above is correct. .<br><br>It is not known whether these tests are carried out by medical device manufacturers as most, if not all manufacturers aren't aware of animal tissues present in polymerisation processes and packaging materials. | ? |
| 8.3. | Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened. | The devices are delivered in a sterile state and are designed, manufactured and packaged in non-reusable materials that ensure their sterility is maintained when placed on the market. | P |
| 8.4. | Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method. | The devices have been manufactured and sterilised by appropriately validated methods | P |
| 8.5. | Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions. | The devices are manufactured in appropriately controlled conditions for sterile devices | P |
| 8.6. | Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk | The devices aren't supplied non-sterile | P |

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| | of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer. | | |
| 8.7. | The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition. | There are no identical or similar products sold in both sterile and non-sterile conditions | P |
| 9 | Construction and environmental properties | | |
| 9.1. | If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use. | Some surgical scaffold is designed to be used in combination with trocars. Not all devices used in surgery are CE marked according to the MHRA at the 2018 MedTech Conference in Coventry. This means that surgical mesh may be used in combination with non CE marked devices.<br><br>Surgical mesh is designed to be cut by healthcare professionals using sterile scissors, that doesn't sear the edges of the polypropylene as is done with ultrasonic devices during manufacture.<br><br>On cutting mesh with scissors, it a leaves sharp cross section of filaments at the point where the knit structure is interrupted and fragments break away from the device. | F |
| 9.2. | Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:<br><br>the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,<br><br>risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,<br><br>the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,<br><br>risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism. | There is risk of injury in connection with physical features of the device as filaments break off and it hardens and cuts through tissue and organs Environmental conditions such as magnetic fields etc. aren't applicable.<br><br>Risk of reciprocal interference is not applicable<br><br>The device has no measuring or control mechanisms where lack of maintenance or calibration could pose any potential risk | F |
| 9.3. | Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to | The intended use of the device does not include exposure to flammable substances or substances which could cause combustion during normal use or single fault conditions | P |

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| | flammable substances or to substances which could cause combustion. | | |
| 10. | Devices with a measuring function | | NA |
| 11 | Protection against radiation | | NA |
| 12 | Energy source requirements for medical devices connected to or equipped with an energy source | | NA |
| 13 | Information supplied by the manufacturer | | |
| 13.1 | Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use.<br><br>As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.<br><br>Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions. | The training and knowledge of potential users has been considered and the information supplied allows safe use of the device. The information supplied includes details that identify the manufacturer.<br><br>It is not practicable or appropriate to set out information for safe use of the device use on the device itself. This information is included in the packaging.<br><br>Instructions for use are included in the packaging for every device | P |
| 13.2. | Where appropriate, this information should take the form of symbols.<br>Any symbol or identification colour used must conform to the<br>harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device. | Symbols are used where appropriate and any symbols and identification used conform to harmonised standards | P |
| 13.3 | The label must bear the following particulars | | |
| (a) | the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community; | the name and address of the manufacturer is included and where appropriate the details of the authorized representative is included where applicable | F |
| (b) | the details strictly necessary to identify the device and the contents of the packaging especially for the users; | Details strictly necessary for identification of the device is included | |
| (c) | where appropriate, the word 'STERILE'; | The world sterile is included | |
| (d) | where appropriate, the batch code, preceded by | Appropriate batch code and LOT | |

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| | the word 'LOT', or the serial number; | numbers are included where appropriate | |
| (e) | where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; | The date the device should be used by is stated on the packaging | |
| (f) | where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; | Single use is indicated on the label | |
| (g) | if the device is custom made, the words 'custom-made device; | NA | |
| (h) | if the device is intended for clinical investigations, the words exclusively for clinical investigations; | NA | |
| (i) | any special storage and/or handling conditions; | Special storage and/or handling conditions are included in the information for use | |
| (j) | any special operating instructions; | NA | |
| (k) | any warnings and/or precautions to take; | Insufficient warnings and cautions are listed but these are not residual as the regulation stipulates | |
| (l) | Year of manufacture for active devices other than those covered by (e) This indication may be included in the batch or serial number | NA | |
| (m) | where applicable, method of sterilization; | The method of sterilization appears on the label and information for use | |
| (n) | in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative. | NA | |
| 13.4. | If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use. | The intended purpose of the device is obvious to the user | P |
| 13.5. | Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. | Devices are identified and in terms of batches; there are no detachable components | P |
| 13.6 | Where appropriate, the instructions for use must contain the following particulars: | | |
| (a) | the details referred to in Section 13.3, with the exception of (d) and (e); | The instructions for use does not include the details required | F |
| (b) | the performances referred to in Section 3 and any undesirable side effects; | The information for use doesn't include all undesirable side effects | |
| (c) | if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; | The device is not to be installed or connected to any other medical devices in order to operate as intended | |
| (d) | all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and | Installation, calibration and maintenance is not a requirement | |

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| | frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; | | |
| (e) | where appropriate, information to avoid certain risks in connection with implantation of the device; | Information is included to avoid certain risks on implantation of the device | |
| (f) | information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; | NA | |
| (g) | the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization; | Necessary instructions with regard to sterility are included | |
| (h) | if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I.<br><br>If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request; | NA | |
| (i) | details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.); | Further handling treatment is included with the device | |
| (j) | in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: | NA | |
| (k) | precautions to be taken in the event of changes in the performance of the device; | There are no precautions included in the information for use in the event of changes in performance of the device making harm unavoidable | |
| (l) | precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; | Reasonably foreseeable environmental conditions are included in the information supplied by the manufacturer | |
| (m) | adequate information regarding the medicinal | NA | |

| ER | Essential Requirements | Justification | P/F |
|---|---|---|---|
| | product or products<br>which the device in question is designed to administer, including any<br>limitations in the choice of substances to be delivered; | | |
| (n) | precautions to be taken against any special, unusual risks related to the disposal of the device; | Information on disposal is included in the information supplied by the manufacturer | |
| (o) | medicinal substances, or human blood derivatives incorporated into the device as an integral part I accordance with Section 7.4; | NA | |
| (p) | degree of accuracy claimed for devices with a measuring function; | NA | |
| (q) | date of issue or the latest revision of the instructions for use. | The latest issue of the instructions for use is supplied with the device | |

3.5 Manufacturer's Risk Management File (ERs 1 & 2, MDD)

One of the first steps in the manufacture and design of a medical device is a documented risk assessment that's collated in a risk management file. This is a living document and forms an integral part of the manufacturer's technical documentation.

The purpose of risk management is to ensure all the risks posed by medical devices are properly identified, analysed, controlled, mitigated, verified, documented, monitored, reviewed and updated.

A condition of ER 1 is that when a device is used as intended, it will not compromise the clinical safety of patients, yet all the evidence is there to suggest mesh does in fact compromise the clinical safety of many patients.

When polypropylene is entered into the manufacturer's risk assessment for the purpose intended by the manufacturer, it is analysed. Due to its known ability to break down under oxidative stress in the human body, controls have to be applied to reduce any risk as far as possible, according to ER 2 which states:

'In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

— eliminate or reduce risks as far as possible (inherently safe design and construction),

— where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,

— inform users of the residual risks due to any shortcomings of the protection measures adopted.

The requirement for risk to be communicated to the user and/patient applies to residual risk where appropriate levels of control have been implemented and risk has been mitigated as far as possible. All the warnings and cautions supplied by the manufacturer in the instructions for use are residual risk and not unavoidable, uncontrolled or unpredictable harm.

Unavoidable and unpredictable death, sepsis, nerve damage, severe permanent pain, fibromyalgia, PTSD, fistula, organ damage, and many other mesh related symptoms do not constitute acceptable risk when weighed against the manufacturer's intended performance of surgical scaffold, which again is the reinforcement of bone or human tissue. Neither is it compatible with the high level of health and safety all patients are entitled to expect.

3.6 EC Declaration of Conformity

The final document created prior to marketing, once a CE marketing application has been successful is the manufacturer's EC Declaration of Conformity. This is where the manufacturer who has fulfilled the legal obligations imposed via the MDD, ensures and declares the products concerned, meet the applicable provisions of the Directive.

The abbreviated Essential Requirements Checklist illustrates all obligations cannot be fulfilled for polypropylene implants and their intended application. Therefore an EC Declaration of Conformity cannot be created and any CE marking on polypropylene mesh devices is wrongly affixed according to Article 18 of the MDD.

Where a CE marking is deemed to be wrongly affixed, the safeguard clause, Article 8 of the MDD shall be implemented for nonfulfillment of all applicable essential requirements (Article 3).

4. Systemic Failures – Root Cause

Over the years I have contacted the UK MHRA, Team NB, and one of the UK notified bodies, to raise several red flags about serious systemic failures in industry and to lodge concerns for patient safety.

The failures have nothing to do with the regulations not being adequate, as has been portrayed by the media and, with the introduction of a new set of rules. I firmly believe the regulations are adequate otherwise there would be far more unsafe and ineffective devices on the market today.

But post market surveillance indicates otherwise and medical devices available globally are generally both safe and effective. The systemic failures are spiralling down from the top and until this is addressed, no matter what regulations are in place, the situation will fail to change.

Here are two copies of some correspondence that demonstrates my concerns regarding the root cause of systemic failures in the medical devices industry.

From Joanne@[redacted]

To XXXX@mhra.gsi.gov.uk

To XXXX at MHRA

Date 29.01.2016 17.26

Dear XXXX, Thank you for accepting my connection request. I first tried to contact XXXX XXXX 7 years ago to voice my concerns about serious systemic failures in the medical devices industry. To date I have been unsuccessful.

Recently I have been communicating some of my concerns with XXXX but I have been told that for action to be taken, evidence will be required. Everything is documented in this industry, so plenty of evidence exists but I believe my concerns ended there.

Most manufacturers are trying to act responsibly and they take guidance from the MHRA and CBs which is often incorrect! Compliance requirements globally are not complicated and if responsible manufacturers know what they have to do, they will do it. But while CAs and NBs are misleading manufacturers, they are struggling to know what they are supposed to do and they are wasting a lot of resources on complete nonsense, while critical elements of the CE marking process get skipped, such as material biocompatibility

and risk. As a result, many manufacturers are certified regardless of critical NCs and this does nothing to keep patients and users safe.

Since 1993 many NBs have blatantly failed to fulfil their requirements and are continuing to promote their failures as new requirements! This is evidenced on Team NB's website. I have discussed this with XXXX XXXX at Team NB who insists these requirements are new even though they are nineteen years old. At the same time, they are suggesting five years grace to implement the new MDR and this I find outrageous.

I don't think we should have to wait to see more consequences of these serious deficiencies materialise before action is taken and we certainly shouldn't be waiting for a new MDR to fix things, because it will not as it does not address the root cause.

If something isn't done soon to rectify this problem, then UK engineering is going to suffer a backlash resulting in a complete breakdown in global trade and industry without even considering potential health risks being brought about by this current incompetence.

I could write a book, but I'll leave it there in the hope that my voice will finally be heard so we can take effective steps to rectify the damage already in place and remove this risk to prevent any future recurrence.

I would be grateful to hear your views on this.

Regards,

Joanne

Joanne Davies

Director

Isomed Ltd.

Ms Joanne Davies,
Isomed Ltd.

March 2016

**MHRA**

151 Buckingham Palace Roa
London
SW1W 9SZ
United Kingdom

**www.gov.uk/mhra**

Dear Ms Davies,

**Administrative complaint – MHRA reference 20156/Q4/05**

I have been asked to investigate your administrative complaint (referenced above) submitted to the MHRA's Complaints mail box on 2 March 2016 as a result of the letter you received from XXXXXXXX, Director Devices, dated 8 February 2016.

The complaint was stated as:

*"I would like to raise a further complaint for the response from XXXXXXXX below which is not acceptable where patient safety is at risk. The MHRA cannot mislead industry in this way.*

*I have failed to receive a response since I wrote on the 8th February."*

Also, the email contained evidence that you had contacted XXXX XXXX seven years ago whilst he was working at Eucomed.

Your original communication to Dr XXXX , XXX, was received on 29 January 2016 and was forwarded to XXXX XXXX for a response.

In this email you raised your "concerns about serious systemic failures in the medical devices industry". You claimed that "CAs and NBs are misleading manufacturers" and "many NBs have blatantly failed to fulfil their requirements".

XXXXXXX's reply to this email was sent on 8 February 2016, which was well within the MHRA's 20 working day target, and attempted to address the issues raised in your email.

He also disputed that "*the information given out by the MHRA and fellow competent authorities is incorrect.*"

He pointed out that "*We* (the MHRA) *are only able to take regulatory action based upon specific information.*"

He also disputed that "*the information given out by the MHRA and fellow competent authorities is incorrect.*"

He listed a number of the recent initiatives taken by the MHRA in an attempt to improve the regulation of medical devices, whilst acknowledging that "*no regulatory system is perfect.*"

The first part of your complaint alleges that the MHRA is putting patient safety at risk and is misleading industry. It is difficult to unravel the exact nature of this complaint, as it is not supported by any specific evidence. XXXX XXXX's response refutes these claims and, therefore, there is clearly a difference of opinion between the two parties. This in itself does not constitute sufficient grounds to uphold an administrative complaint.

You go on to say that you have not received a response to your email sent on 8 February 2016. This email made a number of statements regarding the alleged deficiencies of the regulatory system. There is no reason to believe that this email should have elicited a further reply from XXXX XXXX, as he had already stated the position of the MHRA in his original letter. Again, this does not constitute grounds for an administrative complaint on your part.

Finally, you provided evidence that you had previously contacted XXXX XXXX some seven years earlier to raise similar concerns about the regulatory system for medical devices, whilst he was working at Eucomed.

I am unable to comment on any correspondence that was sent to XXXX XXXX prior to him joining the MHRA and in a completely different role to his current position. However, I understand from him that a request to join a social network, to which he belongs in a private capacity, would have been unlikely to elicit a response, as he does not accept invitations from anyone who he is unacquainted with.

In conclusion, I can find no reason to uphold your administrative complaint regarding the correspondence you have received from XXXX XXXX in response to your letter to Dr Ian Hudson on 29 January 2016.

In conclusion, I can find no reason to uphold your administrative complaint regarding the correspondence you have received from XXXX XXXX in response to your letter to Dr XXXX XXXX on 29 January 2016.

The non-specific nature of the allegations regarding the deficiencies of the medical device regulatory system and the various bodies involved in the regulatory processes have made it very difficult to determine the exact nature of your complaint and, in the final analysis, much of the complaint appears to stem from a difference of opinion between you and the MHRA. As such, this would not normally be the subject of an administrative complaint, unless there is very specific evidence of a failure on the part of the MHRA to discharge its regulatory duties.

If you are dissatisfied with the handling of your complaint, you have the right to ask for it to be reviewed by the Administrative Complaints Office (ACO). ACO review requests should be submitted within two months of the date of receipt of the final response to your original complaint and should be addressed to: Administrative Complaints Officer, 5-T, MHRA, 151 Buckingham Palace Road, London, SW1W 9SZ, or by email to mhra.complaints@mhra.gsi.gov.uk. Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of the ACO review, you will have the right to apply to the Parliamentary and Health Service Ombudsman (PHSO) for a decision.

Yours sincerely,

The above MHRA response is a typical example of genuine industry concerns being completely

dismissed and, the lack of the MHRA's understanding of engineering and the regulatory landscape that would enable them to understand the content of my letter and the nature of problems that exist in industry.

Despite this, these failings are well known by many industry professionals. Prior to my letter dated 2016, on the 24th of September 2013, these issues had already caught the attention of the European Commission with their Recommendation on the shortfalls in audits and assessments, performed by notified bodies in the field of medical devices. This recommendation details the NB's failings since the introduction of the 1993 regulations which are communicated in my letter. European Commission Recommendation 24th September 2013

The MHRA has indeed misled industry for many years and continues to do so, by communicating incorrect information to the public. The MHRA's web archives will, or certainly should hold records of changes that were made to their information, at my request, on at least two occasions in the past as evidence of this.

In approximately 2015 the MHRA's website information told the world that after placing medical devices on the market, no further controls were required! This conflicts with many requirements of the MDD such as Post Market Surveillance and Post Market Clinical Follow-up etc. Their regulatory pathway was also misleading and I managed to get them to update this, with great difficulty by November 2015.

At a recent medical devices conference in Coventry, contact lenses were being communicated to delegates as 'not medical devices' by the MHRA, yet there is no doubt they are and fall within the remit of the MDD. They have done since 1993! Case=321/14 in the Court of European Justice on the 15th September 2014 verifies this. I challenged XXXX XXXX regarding his information being incorrect, not only for contact lenses, but breast implants too; my concerns were quickly dismissed as has become the norm.

Case=321/14

**Operative part of the judgment**

*Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products must be interpreted as meaning that non-corrective colour contact lenses featuring designs do not fall within the scope of that regulation, notwithstanding the fact that their outer packaging bears the statement 'cosmetic eye accessory, subject to the EU Cosmetics Directive'.*

(1) OJ C 315, 15.9.2014.

The following two letters include an email from Candia McCullough, Founder of Mesh UK Charitable Trust and the MHRA's response to that letter. It shows the MHRA insists that manufacturers hold the relevant information to allow a surgical mesh manufacturer to apply a CE marking although my table (3.4) in this document illustrates this cannot be done for surgical scaffold according to the manufacturer's intended use.

Wed 28th August
From Candia McCullough, Founder of Mesh UK Charitable Trust
To XXXX XXXX and XXXX XXXX MHRA

Dear XXXX and XXXX,

As we understand, the MHRA still claims benefits of surgical mesh implants, outweigh the associated risks.

Can you kindly send us a copy of your risk analysis and determination for surgical mesh to this effect please? We now have over a thousand members who expect support and reassurance. Without this information we're struggling to justify how any patients can go ahead with surgical procedures that include mesh implants.

Best Regards

*Candia McCullough*

*Founder*

*Mesh UK Charitable Trust*

*Registered Charity no: 1176523*

www.meshuk.org

---

From XXXX XXXX MHRA

To Candia McCullough Founder Mesh UK Charitable Trust

4th October 2018

Dear Candia,

Your email of 22nd August 2018

I'm very sorry it's taken a while to reply, but we've been extremely busy over the holiday period. Thanks for taking the time to write to us and thank you very much for asking people signed up to your organisation to report problems to us. As we talked about when we met, this is very important to us and to working out if there are things we need to do to increase protection and support for patients over time.

In the Annex to this letter I have provided you with the number of adverse incident reports we have received for surgical mesh to treat SUI and POP and hernias (of which there are many types) from the public and from people involved in healthcare. When I read your email, I wasn't sure what you meant by "substantially equivalent mesh", but I think you may mean devices introduced, because they were "equivalent" from a regulatory view.

I would add there are differences in a number of characteristics between brands and indications of use, some of which are refinements and developments introduced following experience with these devices over time. I hope the data I have provided is of some use and hopefully goes a long way towards answering your questions.

Also, when we met in July, we talked about how our current position is based on a wide variety of evidence and draws on the findings of a number of studies and reports which have been conducted over time. We also have considered the data from other things, including adverse events reported to MHRA by patients, clinicians and manufacturers. You may recall in the email to you in July, following the meeting we had, it had links to several of these and I hope this was helpful to you. I've included the information from the previous email for your information to save you looking it out again.

***From a regulatory perspective the reason these medical devices are still available in the UK is because their manufacturers have demonstrated their devices have conformed to the requirements of the current legislation in the EU.*** This process makes many demands on manufacturers and includes clinical information, as well as details about the materials and their safety, plus risk assessments and the benefits the manufacturer says their devices have.

On that note, just to clarify, the mesh manufacturers are the ones who must show what the benefits and potential risks of their devices are, so it's not MHRA's remit to do this. Manufacturers provide MHRA the information on this to an independent assessment organisation called a Notified Body who review this information among others and decide whether to give them CE Certification. In general, our job is to oversee the post-market surveillance system and audit the Notified Body activities to make sure manufacturers and Notified Bodies are doing what they should be. If they are not, we will consider taking action to continue to protect the public.

It's important and cannot be stressed enough the final piece of the benefit and potential risk conversation should always be between patients and their doctors, again this is something I'm sure we spoke about in July. We always fully support informed consent where patients get the information about their procedure and any medical devices which may be used by their clinician. Once patients have this they can then decide what is the best option for them (surgical or otherwise). If this conversation isn't being conducted as it should, it's a serious clinical matter.

Having said all that, just to pull this all together, based on the current evidence, no other regulator in Europe, USA or Canada has acted to remove mesh devices from use in their countries, because they feel, as we do, manufacturers have conformed to the relevant regulations. It is true Australia and New Zealand have restricted the availability of some specific devices, but surgical meshes in general remain available in Australia and New Zealand.

The other thing to add is these other countries aren't so fortunate as us, because they don't have the National Institute for Health and Care Excellence (NICE) to produce clinical guidance to the NHS and clinicians. Whilst there is no legal requirement to comply with the recommendations NICE make, it is considered best clinical practice for the NHS to follow their guidance on procedures and not doing so would need a very good clinical reason. Their advice on their safety and efficacy on devices used in procedures draws on the best evidence available at the time they are produced.

Another advantage we have had, as we talked about when we met, is we've been involved in several reviews and reports, such as the ones which took place in Scotland and England in the past few years. To help us further, we also work regularly with NICE, professional organisations and the NHS across the UK. This is good, because we regularly have contact and discussions about these devices and what we keep being told is clinicians still strongly believe

many patients benefit from the use of these devices. Of course, they are also acutely aware some patients have serious complications.

So, what we would say in support of patients, is for anyone who has a distressing problem, if surgery is most likely to help there should be certain things in place and this would be when all other types of treatment have been thought about or tried. The most important thing though, is the patient should get the information they need to decide, if having considered or exhausted other options, they want surgery. If they do, it should be carried out following NICE guidance, the recommendations of the "halt" in Scotland and the "pause" in the rest of UK. This is because we firmly believe the decision to have treatment using surgical mesh should be between the patient and their clinician and should done only by thinking about their personal circumstances.

To add, one of the other advantages we have in the UK is a great deal of work has been undertaken by patients, healthcare professionals and professional organisations to ensure the consent process is properly informed. This was done in great detail in Scotland, both before and during their review and relooked at during the English review. In each case patient input was really strong and was essential to what was produced.

We and all those involved take yours and other patient's concerns very seriously. Hopefully what you will agree is we should also hear of the experiences of patients who have had successful procedures. We shouldn't prevent patients with distressing and disabling conditions, which can't be fixed in any other way, the chance to have a procedure, which for the vast majority helps them to improve considerably.

If there is any other information you need, or if I can help with something else, please let me know.

Best wishes,

---

Many manufacturers throughout Europe are failing to fulfil their legal obligations due to the superfluous paperwork imposed on them by NBs, while critical elements, such as Essential Requirements are regularly omitted.

In contrast some NBs are communicating misleading information to manufacturers, informing them of 'abbreviated technical file' requirements that are little more than a CE marketing application summaries. This does not comply with the MDD that stipulates all applicable essential requirements shall be fulfilled, which includes full technical data for every device manufacturer, including those that have no involvement with a NB.

The following link leads to a document commissioned by the Dutch Health Care Inspectorate. It is an evaluation of manufacturer's technical files that illustrates similar shortcomings to those I've highlighted in the table above (3.4) for surgical scaffold, and for 'abbreviated technical files; and unfortunately also represents a general reflection of many UK medical devices industry failings due to misinformation from the top.

https://zorgnu.avrotros.nl/fileadmin/user_upload/silicone-breast-implants-in-the-netherlands-2.pdf

I believe that problems with surgical scaffold, could certainly have been anticipated and acted upon sooner by the regulatory authorities, but they aren't prepared to listen.

Most recently at an MHRA meeting in July 2018 I communicated to XXXX XXXX that some manufacturers don't know what materials are in their products. He quickly contested this claim. I went on to explain how I had asked a client if they could verify the materials in their implants and they could not. So I called their supplier in the US to see if they could verify this, they couldn't either. This ended up in a call to the Chinese supplier who told me, he didn't know why I was asking and had never been asked that question before! The material in question was for permanent implants. This information is critical, not only from a patient safety perspective but to protect the environment on safe disposal of these devices as well.

5. Records and Traceability

According to many patients, they have had mesh implanted without consent. This has been confirmed by way of an apology from Emma Hardy MP in the Houses of Parliament this year. Hospitals are claiming records are limited, so it is impossible to accurately gauge the magnitude of surgical mesh problems, a solution exists.

A full set of records not only lies within the hospital's purchasing department, there are more records in several departments including theatre kitting lists, stores documentation and hospital invoices etc. The NHS has their own Quality Management Systems where full record keeping is a requirement of those management systems. So full records do exist somewhere. They just have to be retrieved.

Most records remain with medical device manufacturers and other economic operators for sales and distribution purposes etc. throughout the whole of the supply chain. They are maintained by economic operators and manufactures for full traceability purposes. Traceability is not stated as a legal requirement of the MDD, it is required though as part of every manufacturer's Quality Management System. Traceability is of paramount importance and an absolute necessity in any engineering environment, regardless of regulatory requirements.

These requirements are in place to ensure medical device manufacturers have full traceability of their devices in the event of a recall etc. Every medical device manufacturer uses these systems and without them, they cannot be certified by notified bodies. Every medical device manufacturer also holds full records of sales/returns etc. that is not company sensitive data and does not fall within confidentiality provisions of Article 20 of the Medical Devices Directive.

The legal retention period for documentation in the case of surgical mesh is at least fifteen years for manufacturers.

**6. Summary**

The mesh issue is being supressed on television and in the newspapers as a hernia or transvaginal issue, but it isn't. There are older people in our communities and care homes, with no internet access who still have no idea what has happened them, along with many others. It's an issue that includes approximately 300 substantially equivalent devices and everyone needs to be informed, needs an explanation, and is entitled to apology at least; with the reassurance that this is never, ever going to happen again in the medical devices industry.

It's what we already preach in industry with regard to Thalidomide and it's what certified Quality Management Systems are for.

The fact that any medical device is being put into people that can't ever be guaranteed to be fully removed, is absolutely unthinkable and sickening.

We are already twenty five years on since the 1993 regulations were published in the Official Journal of the European Union and they have still not been implemented in their entirety. And to say we already have new regulations in their transitional period that don't have to be fully implemented until 2020, isn't going far enough.

We need to act now to ensure that all devices manufactured in the UK comply with current (1993) regulations to protect patients and allow them the high level of health protection and safety everyone is entitled to expect.

In applying the 1993 Rules, as stated above (3.6) where CE markings are wrongly affixed the safeguard clause (Article 8, 93/42/EEC) shall be implemented.

When people don't do what is supposed to be done, it is usually because they don't understand the process. This also needs to be addressed and rectified with independent and accountable regulators, who need a proper understanding of engineering principles, manufacturing processes, materials, Quality Management Systems; and the regulatory pathways that are there to ensure only safe and effective medical devices make it to the market, as laid down by the Treaty.

# Sling the Mesh Campaign

**Submission of Evidence and Recommendations for the Independent Medicines and Medical Devices Safety Review**

**24 October 2018**

**Owen Smith MP**

HOUSE OF COMMONS

LONDON SW1A 0AA

Baroness Cumberlege
Independent Medicines and Medical Devices Safety Review
King's College London
Guy's Campus
London
SE1 1UL

24 October 2018

Dear Baroness Cumberlege,

**Re: Call for evidence: Independent Medicines and Medical Devices Safety Review**

The attached submission from Sling the Mesh sets out twelve priority areas to be considered by the review.

Since I began campaigning on the issue of pelvic mesh, I have received contact from hundreds of women sharing their heart breaking experiences of complications following mesh surgery. MPs from all parties have joined the APPG on Surgical Mesh Implants after being alerted to the horrors of mesh injury by constituents whose lives have been changed for the worse after surgery.

For too long clinicians, manufacturers and regulators have failed to listen and take seriously the concerns of the thousands of women who have been injured by mesh. I am pleased that you have taken steps to ensure patients are listened to in this review, and that you have recommended a suspension of mesh while you gather evidence.

As stated previously, I believe it is essential that this review examines the medical evidence of the safety of the use of mesh as it is evident that there are clear flaws in the complication rate of 1-3% repeatedly used by MHRA and NICE. The current processes of device regulation, approval and the reporting of adverse effects must also be improved. Patients and clinicians agree that MHRA's yellow card system has failed in its objective to monitor the safety of mesh devices.

It is clear that devices like mesh have been aggressively marketed without having to undergo strict clinical trials. The MHRA must learn from the mistakes of mesh and ensure devices are subject to strict long-term trials and data is gathered on adverse events before devices are approved and implanted.

10 Market Street, Pontypridd, CF37 2ST
owen.smith.mp@parliament.uk
www.owensmithmp.co.uk
Twitter @OwenSmith_MP
Tel: 01443 401122

I welcome the recent draft NICE guidelines *Urinary incontinence and pelvic organ prolapse in women: management* however I believe that it must be made clear that mesh should only be used as a last resort, when other treatments and procedures have failed. More must be done to improve general pelvic floor health, including the implementation of a continence care pathway with physiotherapy at its heart. I hope the review will recommend improvements on current maternity care to ensure pelvic floor health is prioritised.

I am pleased that you have listened to the APPG's call for a full prospective registry of mesh surgery. It is important that when problems are reported to clinicians, they are recorded within all structures of the NHS and private practices - for example GP practices, A&E, mental health departments, pain clinics - to ensure the registry provides an accurate reflection of complications.

There should also be an overhaul of the HES reporting system to include all mesh procedures. As you are aware, we still do not know the true extent to the number of complications of mesh and I regularly receive contact from people suffering problems from various types of mesh procedures including pelvic, rectal and hernia surgery.

Improved processes must be put in place quickly to ensure a multi-disciplinary approach for mesh removal surgery. Patients tell me that the few specialists in the UK who remove mesh have long waiting lists, and often women are not able to access the specialist advice they require.

I am pleased that you have provided a counselling hotline for the duration of this review and I ask that you will consider creating a permanent support system for women dealing with mesh injury. As you know, many women suffering from mesh injury may feel embarrassed to speak to friends, loved ones and even doctors about their complications, often making their experience very lonely. I know Sling the Mesh are often contacted by women who feel suicidal. I hope that you will prioritise access to support for mesh injured women.

Mesh surgery has exposed women to unacceptable risks, and those affected by life-changing complications should be entitled to compensation. The issue of legal timeframes is a cause for concern- many who have suffered horrendously after mesh surgery cannot pursue a legal case as they are outside the Statute of Limitations. A lack of awareness of mesh complications by clinicians, patients and the general public has meant that many sufferers were not aware that their health problems were associated with mesh until very recently.

Thank you for considering the points raised in this letter and in the attached submission from Sling the Mesh. I have written to you prior to the call for evidence and would be grateful if you would also take into consideration my previous correspondence.

Kind regards,

Owen Smith

**Owen Smith MP**
Chair of the All Party Parliamentary Group on Surgical Mesh Implants
Member of Parliament for Pontypridd

*"STM campaigners feel that the greatest way to combat the use of mesh and its terrible consequences is to shine a light on the injuries and scars suffered by thousands of women suffering in silence with pelvic mesh. By that we mean physically, emotionally, socially and economically; to hold them before the eyes of those accountable and force the realisation that thousands of UK mesh injured women's wounds are real and the consequences are life changing. These women deserve justice.*

*Ensuring women's voices are heard, serves to remind us that we can bring about positive change; moving us closer to a permanent ban of pelvic mesh and improved social justice in medicine. This includes greater quality assurance and levels of accountability, with ethical and professional healthcare that meets our needs. For women suffering from pelvic mesh complications and injuries the social contract has eroded terribly."*


Submitted by: Kath Sansom, Michelle Moffatt, and Julie Loxley, with additional contributions, advice or personal stories from STM team members, Ms Sohier Elneil (Annex 14) and Thompson's solicitors (Contributions to Chapter 8).

Contact: slingthemesh@gmail.com. https://slingthemesh.wordpress.com/

## STM Submission of Evidence and Recommendations for the Independent Medicines and Medical Devices Safety Review

Table of Contents

**List of Annexes**

1. Detailed statement from STM N Ireland and Wales
2. STM 2017 survey results on type of pelvic mesh complications
3. STM 2017 survey results on how mesh has affected women's lives
4. STM 2017 survey results on the length of time a mesh has been implanted
5. Missing data from HES Digital Audit report April 2018 and responses to report
6. Detailed timeline of mesh device events
7. Case study: economic, emotional and physical costs of mesh injuries
8. Women's mesh complications identified by translabial ultrasound scan
9. The British Pain Society Press Statement on Suspension of Mesh in NHS hospitals
10. Photographs of pelvic mesh device before implant and after excision from body
11. Photographs of mesh complications suffered by members of STM
12. Alternatives to pelvic mesh surgeries
13. MHRA table of data of 13 mesh related deaths
14. Mesh and Surgical Removal by Dr Soheil Elneil
15. STM survey 2018 results

## Purpose of Sling the Mesh (STM) submission

The purpose of this STM submission is to recommend on behalf of mesh-injured women throughout the UK for twelve key priority actions to be considered in the Review. This is to ensure that the Review responds comprehensively and transparently to a history of denial, ignorance, misinformation and lack of accountability relating to the mesh device scandal. This submission has been written by the STM team and reflects the views of STM members. STM received input from Thompson's Solicitors on action 8 and Ms Soheir Elneil in Annex 14. Annex 1 includes detailed statements from our members in N. Ireland and Wales**.**

It is increasingly recognised globally by clinical and science researchers and the medical and regulatory communities, that polypropylene pelvic mesh devices are not biocompatible in the human body and therefore not fit for purpose. Women fitted with all types of pelvic mesh devices suffer from physical injuries with emotional, social and economic consequences for them and their families.

Due to the lack of adequate warnings of multiple risks related to pelvic mesh devices directed at both the women seeking a solution to POP or SUI and their treating clinicians, pelvic mesh has caused avoidable injury; and has been implanted without informed consent. Court cases in America have examined evidence that mesh manufacturers have destroyed and played down information about mesh complications. According to NHS Digital figures, between April 2008 and March 2017, more than 127,000 women in England alone were treated with pelvic mesh implants, also called tapes and slings. According to available figures 100,516 patients had a mesh tape insertion procedure for stress urinary incontinence and 27,016 patients had a mesh insertion procedure for urogynaecological prolapse. This does not include women implanted with mesh in private hospitals. Mesh procedures began in 1997, yet the number of mesh-injured women in the UK is unknown due to vast weaknesses in reporting and flawed research. The STM support group alone has increased to more than 7,000 members and is growing daily in numbers.

Complications associated with pelvic mesh procedures include haemorrhage, mesh erosion resulting in organ perforation, nerve damage leading to disability, infection, chronic pain, de novo dyspareunia and loss of sex life; all of which often requires further surgeries and huge costs to the NHS and to women paying for private treatment. However, there is uncertainty about the rate of complications intra-operatively and post-operatively in the longer term. In a 2017 STM survey of 560 women with mesh implants, all respondents reported complications as a result of their mesh device (see Annex 2).

There is increasing concern that complication rates are much higher than previously identified. Four systematic reviews have identified a lack of long-term outcome data (see references Latthe et al, 2007; Nambiar et al, 2014; Ford et al, 2015; Novara et al.) Keltie et al 2017 conducted an 8 year study of 92,246 women to assess the rate of adverse events from mesh procedures for stress urinary incontinence in England from 2007-2015. Cases were identified from the HES database. The complication rate within five years of mesh procedure was 9.8 per cent. This figure is far higher than the 1-3 per cent complication rate stated by MHRA and NICE based on a flawed set of studies.

The PROSPECT study, is deemed the most robust and up-to-date evidence for the use of mesh and grafts in vaginal POP surgery. The study reported vaginal repair for prolapse with mesh or biological graft material did not improve women's outcomes in terms of effectiveness, quality of life, adverse effects, or any other outcome in the short term relative to non mesh repair but 12 percent of women had a mesh complication after only two years follow up. The study stated implantation of any mesh for the treatment of prolapse via the vaginal route should only be considered in complex cases in particular after failed primary repair. "Therefore, follow-up is vital to identify any longer-term potential benefits and serious adverse effects of mesh or graft reinforcement in vaginal prolapse surgery."

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31596-3/fulltext

Commenting on the PROSPECT study, in **BMJ opinion 3.1.17,** Richard Lehman stated, "If you happen to be a woman with the said prolapse, avoid mesh. This is the moral of the PROSPECT trial… The trial was the first adequately powered one to compare the outcomes of anterior or posterior vaginal prolapse repair involving either synthetic mesh inlays or biological grafts against standard repair in women."

https://blogs.bmj.com/bmj/2017/01/03/richard-lehmans-journal-review-3-january-2017/

The continued use of pelvic mesh in the UK, and the number of individuals affected, is evidence of a history of failures, particularly regulatory and adverse event reporting, relating to the safety of mesh devices used to treat SUI and POP. Refer to the following link highlighting a timeline for transvaginal mesh safety concerns from 1996 to the present. A further detailed timeline can be found in Annex 6.

https://www.cebm.net/2017/12/transvaginal-mesh-timeline/

In STM's view the pelvic mesh scandal represents failure of all ethical principles, one of the most important of which is the issue of lack of informed consent. The lack of respect for patient autonomy and honesty through appropriate counselling of all expected benefits and risks, based on clinical evidence, has led to informed consent not being obtained through a shared decision-making process which has exposed thousands of women with pelvic mesh to harm. Those women affected pay the highest price without any acknowledgment on the part of manufacturers or regulators of the role that they have played in creating and prolonging the incidence of mesh injuries in women in the UK; and crucially they do so without compensation.

Against this backdrop, this submission sets out the case for the following actions:

1. A full ban in the use of pelvic mesh devices following the Review. If this is not achieved then mesh to be offered as a third and final option once conservative methods and non mesh surgeries have failed.
2. Visit the science: unbiased review of the science of mesh use in the pelvis and the properties and safety of polypropylene material in the human body over time;

3. Review of the structures and processes of mesh medical device regulation, approval and adverse affects reporting to enhance transparency and safety;
4. An overhaul of the HES reporting system to ensure ALL mesh complications are recorded for a patient's lifetime and to retrospectively correct the vast underreporting of mesh complications to date through a national recall;
5. Review the governance, accountability and effectiveness of the medical profession, including relevant institutions responsible for regulation, monitoring and evaluation of the safety of mesh implants in the NHS and private sector.
6. Improved processes to enable mesh-affected women to access fast-tracked quality assured multi-disciplinary services for full mesh removal surgery;
7. Compensation to be paid to all those affected by pelvic mesh in the UK;
8. Review limitation periods for litigation for medical negligence and product liability claims for mesh injured women;
9. Development of a registry of pelvic mesh implants to track mesh devices and complications;
10. Consider the effects of commercial influence on the published research on mesh and the introduction of a Physicians Sunshine Payment Act to ensure greater transparency
11. Consider the need for a full Public Inquiry or Royal Commission;
12. Ensure transparency of this independent Review;

## About Sling the Mesh

Sling The Mesh (STM) was founded in 2015 by Kath Sansom, to initially support women suffering complications from mesh devices implanted to treat stress urinary incontinence (SUI) or pelvic organ prolapse (POP). It began with 20 members in 2015 and by 2018 has grown to more than 7,000 including members who have suffered complications from ventral rectopexy, sacrohysteropexy, sacrocolpopexy and hernia mesh implants. Similar complications of pain, erosion and foreign body response have been experienced by those implanted with mesh implants, along with the medication for pain relief.

The group's purpose is to provide support, raise awareness in the media and lobby Parliament for a ban in the use of pelvic mesh. In addition we are an information source highlighting global research on mesh. We are the long term, living evidence that mesh causes life changing injuries in the human body, yet we have been ignored for far too long.

The following sections of the report provide more background on the key issues and full details on each of the 12 STM Actions listed above.

It should be noted that the submission needs to be read in full including the references and annexes as the contents in each section are not mutually exclusive.

**Glossary**

| | |
|---|---|
| APPG | All-Party Parliamentary Group |
| BAUS | British Association of Urological Surgeons |
| BMJ | British Medical Journal |
| BJUI | British Journal Urology International |
| BSUG | British Society of Urogynaecology |
| EC | European Commission |
| EU | European Union |
| FDA | Food and Drug Administration (in the United States) |
| GMC | General Medical Council |
| HES | Hospital episode statistics |
| HQIP | Health Quality Improvement Partnership |
| IUGA | International Urogynaecological Association |
| J&J | Johnson and Johnson |
| MDSO | Medical Device Safety Officer |
| MHRA | Medicines and Healthcare Products Regulatory Agency |
| NICE | National Institute for health and Care Excellence |
| POP | Pelvic organ prolapse |
| RCOG | Royal College of Obstetricians & Gynaecologists |
| RCT | Randomised controlled trial |
| SCENIHR | European Scientific Committee on Emerging and Newly Identified Health Risks |
| SERNIP | Committee on the Safety and Efficacy Register of New Interventional Procedures |
| STM | Sling the Mesh |
| SUI | Stress urinary incontinence |
| TOT | Transobturator tape |
| TVT | Tension-free vaginal tape |
| TVT-O | Tension-free vaginal tape (obturator) |

## Introduction

There was little information available, if any, for patients about pelvic mesh prior to it being approved for market since mesh manufacturers have not been required by the U.S. Food and Drug Administration to conduct any clinical trials. Instead mesh devices were introduced to the market to treat POP or SUI in the mid 1990s with copious marketing promises and no proper research to back up their introduction. Doctors and marketers considered accurate placement of the mesh for SUI and POP was all that was necessary to deem it a success.

Mesh has been used to treat SUI and POP for the past 21 years because it overcomes the need to use traditional techniques such as Burch Colposuspension and autologous slings using native tissue. It is said to be less invasive; takes less surgical and hospital bed time; and has been thought to reduce the risk of recurrent prolapse.

Transvaginal mesh made from polypropylene is used to treat SUI. This procedure involves creating a bladder sling using a strip of mesh (referred to as tape or sling) that is inserted through vaginal and abdominal incisions. The most commonly used SUI mesh has been the TVT retropubic sling. Transobturator (TVT-O/TOT) and single incision short mesh sling procedures have also been used.

Similar techniques have been used to treat POP, with mesh made from the same material used to support the tissues that hold the vaginal walls, uterus, or rectum in place. Concern has increased that use of mesh devices to treat SUI and POP has exposed many thousands of women in UK to avoidable harm.

The actions requested in this report apply to all pelvic mesh. This includes abdominally placed prolapse mesh to treat vaginal and colorectal prolapse, which we say all falls within the remit of the Government review of pelvic mesh.

Abdominally placed mesh prolapse surgeries currently in use are:

1. Sacrocolpopexy, to repair vaginal vault prolapse following hysterectomy.
2. Sacrohysteropexy, for repair of uterine prolapse.
3. Ventral mesh rectopexy, for repair of rectal prolapse or intussusception.

STM wishes to point out that abdominally inserted prolapse mesh patches are made from the same materials as transvaginal prolapse mesh, supporting some of the same organs, causing the same serious complications in many women as vaginally inserted prolapse mesh. So these too should be a cause for concern.

• A nuance of language with the media mostly referring to this issue as the vaginal mesh implant disaster means that some surgeons seem to think it is acceptable to say only transvaginally placed prolapse mesh is a concern. Abdominally placed prolapse mesh can have same serious complications as the vaginally placed option

• A recent Sling The Mesh survey (Annex 15, Figure 1) shows our prolapse mesh membership is split between those who had it placed vaginally and who had it placed abdominally, with a total of 16 per cent having a type of abdominally inserted prolapse mesh vs. 11 per cent having transvaginally inserted prolapse mesh

• We know surgeons believe bacterial contamination is more likely with transvaginal insertion as the vagina is not sterile but when you are dealing primarily with a plastic implant that can change once implanted in terms of shrinking, going brittle degrading and harbouring bacteria the risks of that are universal regardless of placement.

• STM believes it is clear that complications are under reported for all types of mesh, including abdominal prolapse mesh.

This Review is welcome but overdue. STM believes that so many of those who received this treatment were pushed into surgery when other, safer, more conservative treatments were also available, but not offered. It clearly has not been in many women's interests and they would certainly not have chosen pelvic mesh devices had all the potential risks and consequences been properly explained to them (see Annex 2 for full list of pelvic mesh complications). It begs the question whether the so-called cheaper mesh option was used so extensively to suit the surgeons and the NHS budget; and to speed patients through the system.

STM believes the use of pelvic mesh and its removal has been mishandled across the UK. It was mis-sold to women as a 'quick fix' but what knowledge did surgeons have of its potential complications in the longer term? Were surgeons in full possession of the facts when they failed to adequately warn and gain proper consent from women? Did surgeons fail to adhere to the requirements of their professional bodies for their continuing professional development by failing to keep abreast of the science and research papers published on mesh? Did the use of mesh become so extensive and so pervasive that training was minimal? Did financial incentives of the mesh manufacturers influence the widespread use of mesh? Why were so many women ignored when they reported post-mesh complications to their implanting surgeons, and did this contribute to underreporting in official statistics? There are

many unanswered questions that STM hopes this Review will answer in a thorough and unbiased manner.

STM recommends the following 12 Actions be considered by the Review team. Specific recommendations for each of the 12 Actions are outlined at the end of this submission.

## Action 1. A full ban in the use of pelvic mesh devices following the Review.

1.1 STM welcomes the Review team's decision to "pause" the use of transvaginal mesh to treat SUI and POP for the period of the Review. This goes some way to allaying concerns by those affected by mesh devices and the public at large that the Review has not already made its decision regarding the use of mesh and that patient safety is being taken seriously. In addition, it goes some way to mitigating an already strong feeling of a lack of trust of government and medical institutions responsible for women's health care specifically relating to mesh complications; and a suspicion that some of those undertaking the Review may be conflicted. Furthermore, if the review finds that mesh poses an unacceptably high risk to women, the Government and NHS will not now be vulnerable to successful litigation claims, from those women implanted during the Review period who develop mesh related complications now or in the future.

1.2 STM advocates a cautious approach by the Review team, and recommends all the data is evaluated by the Review to establish the safety and efficacy of vaginally implanted and abdominally placed synthetic mesh and biological graft devices. Severe complications affecting the quality of life of many women have occurred from immediately after surgery to over a decade after mesh device implant. In the absence of robust monitoring data of adverse events and unbiased longitudinal research studies over a long period of time for women implanted with different types of mesh devices, it is simply not safe to implement on the scale that it has. STM is now using the term pelvic mesh, rather than vaginal mesh, to include the growing numbers joining STM suffering from complications as result of ventral mesh rectopexy, sacropolpopexy and sacrohysteropexy. STM also has members, including males, suffering from complications due to hernia mesh, though we recognise that hernia mesh is outside the remit of the Review.

1.3 NICE has launched its consultation into revised guidelines for treatment for SUI and prolapse and mesh removal. Revised guidelines are due to be published in 2019. The finalised NICE guidelines must incorporate the findings of this Review. If a ban on mesh is not achieved then the revised NICE guidelines should state that mesh should only be offered as a last resort option for women after conservative treatments and non mesh surgeries have failed.

1.4 NHS England are currently developing service specifications for the management of mesh complications and the finalised specification must incorporate the findings of this Review.

1.5 In 2014 the Scottish Health Secretary called for a suspension of transvaginal mesh implants and STM is relieved that four years later England and Northern Ireland has implemented a similar suspension – hopefully shortly followed by Wales. STM also advocates for the suspension of abdominally placed mesh.

1.6 In response to the Review team's recommendation to temporarily suspend SUI mesh pending the outcome of the review, the BSUG press release on 10th July 2018, written by its Chair, Prof Duckett, states, "This decision is not based on any scientific logic or thinking. This is the single most researched incontinence procedure in the world and to therefore place a suspension on its use contradicts all the research, scientific evidence and guidance issued by national bodies." Prof. Duckett's comments contrast significantly with previous recent studies he has conducted:

- "There is little objective evidence regarding complication rates for mesh procedures outside clinical trials. Current coding poorly collects complications of prolapse and continence surgery using mesh… Only 27 per cent of surgeons report all of their mesh removals because it is not mandatory to do so." (Duckett et al July 2017). https://link.springer.com/article/10.1007/s00192-016-3217-z

Another study concluded, "The overall 3-year failure rate was 52.6 per cent in the single incision sling group and 9 per cent in the retropubic mid-urethral sling group. Both procedures had reduced efficacy over time." (Duckett & Basu December 2013). http://link.springer.com/article/10.1007/s00192-013-2125-8

## Action 2. Unbiased review of the science of mesh use in the pelvis and the properties and safety of polypropylene material in the human body over time

The Review team has stated they will assess historic scientific evidence on pelvic mesh and whether the scientific evidence underpinning current regulatory and clinical practice fully and properly reflects:

a. The long term quality of life impact where there are adverse complications following these pelvic mesh procedures;
b. The innate properties of the polymeric material currently in use in the manufacture of pelvic mesh products and what is known about how those properties change once the mesh has been implanted in the human body and over time;

STM believes that the scientific evidence on pelvic mesh implants needs to be properly reviewed by an unbiased source not connected to any surgeon society. This Review needs to take into consideration the vast body of evidence from patient voice as this evidence is not captured in the trials and research papers. Intended and/or reported outcomes do not tally with user experience. Without long term robust evidence a lot of the "science" will not give a real life picture. Any mesh implanted has an element of a potential ticking time-bomb. STM has members who have been healthy for months or years and then suffer complications. In one case, a woman's mesh implant cut through her urethra after 16 years. She, and women like her, will not feature in short term trial results. Patient voice is key.

STM provides an overview of this as it relates to frequently used types of pelvic mesh. STM has also considered the issue of the properties and safety concerns of polypropylene mesh material in the human body over time.

### 2.1 Scientific evidence for pelvic mesh use for SUI

2.1.1 The key issue that has perpetuated pelvic mesh use over the past 21 years has been the flawed studies that focus on efficacy as opposed to new onset of complications such as chronic pain, infections, dyspareunia/loss of sex life, mesh erosion. If trials only focus on whether the mesh has addressed the problem for which it was intended then it is deemed a success. Frequent disregard of a raft of severe complications that mesh can bring in its wake, has resulted in studies favouring mesh compared to the traditional procedures. Mesh can result in an additional layer of life changing and unacceptable risks. This means much of the research has given surgeons, the NHS, regulators and patients a false reassurance of safety. A review of Quality of Life questionnaires used in research reveals that most were never designed to capture these complications, leading to the situation we have now of so many women maimed with life changing injuries and health problems.

2.1.2 One of the focus areas of the Review is whether the processes pursued to date, when safety concerns have been raised by patients and others, have been sufficient and satisfactory. STM believes they have not been. The main reason why patients' mesh concerns were not listened to and acted on is because for many years, the Government, NHS, health leaders and regulators kept referring back to the scientific studies with low complication rates. Women negatively affected by mesh tried to get their voices heard for years but were ignored. Only when thousands of women joined together and became more vociferous, has the spotlight been focused on a serious situation that highlights it is not just a small minority suffering. STM will look at the issues and how it relates to each type of pelvic mesh in use in the UK.

2.1.3 The early SUI mesh studies never captured the true scale of the devastating and life changing complications of mesh implants because the focus of most of the studies were on efficacy rather than safety and related complications. Many early studies on SUI mesh quoted low complication rates of 0 to 3 per cent. These studies were then quoted by the MHRA and other medical bodies as evidence that mesh was safe. The MHRA's 2012 York report lists the studies it used in coming to the conclusion that transvaginal SUI mesh had a complication rate of 1-3 per cent. The York Report was relied on by the MHRA and other bodies for a long time to keep saying that "benefits outweigh the risks" and that "adverse event rates associated with the various surgical techniques using vaginal tapes for SUIs are generally in the range 1-3%."

The York report:

http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con205383.pdf

Sample study:

https://link.springer.com/content/pdf/10.1007%2Fs00192-007-0334-8.pdf

2.1.4 More recently, analysis of the NHS Hospital Episode Statistics for transvaginal SUI mesh insertion and hospital readmission 2007-2015, published by Keltie et al in the journal Nature, has demonstrated a complication rate of 9.8%. This is the largest study to date of surgical mesh insertions for SUI with coverage of NHS patients over an eight year period. This study acknowledges that the true complication rate is likely to be higher still as this figure misses out women who developed symptoms following mesh surgery but were dismissed by a surgeon, or were seen as an outpatient or were seen by a GP as being unrelated to mesh. Also it does not include private hospital data. The NHS's own data disproves the MHRA's figure of 1 to 3 per cent. STM notes that the Keltie study has not been included in more than 800 pages of scientific literature provided as evidence for the new NICE draft guidelines.

https://www.nature.com/articles/s41598-017-11821-w

2.1.5 The Ward Hilton study is the largest RCT of mesh vs non mesh procedures- Burch Colposuspension vs TVT. But this study too did not give a true picture of the complication rate, as it focused on improvement of SUI as opposed to long term complications and health problems caused from the mesh implant. The study was carried out in 2002 and then at 2, 4 and 5 year follow up, with the last follow up published in 2008. The complications rates of mesh based procedures rise as the years progress. An additional concern with this study is that it received funding from Ethicon, a subsidiary of Johnson & Johnson that produces TVT devices.

https://slingthemesh.files.wordpress.com/2018/10/ward-and-hilton-2002-bmj.pdf

https://slingthemesh.files.wordpress.com/2018/10/ward_et_al-2008-bjog_3a_an_international_journal_of_obstetrics_gynaecology.pdf

2.1.6 A study by Nilsson et al with 17 years follow up for implantation of TVT has been frequently cited by mesh manufacturers in support of its long term safety. However, the study had significant flaws including a small cohort of just 58 women (12 of whom were interviewed by phone). The 22 per cent drop out from the original cohort of 90 women introduces a severe bias. It is well recognised in science that even a drop out of 5 per cent introduces bias to the figures. In addition the study was run by two trial authors who state in the study that they are paid consultants for Ethicon, a subsidiary of Johnson & Johnson, the main manufacturers of the pelvic mesh implants to treat SUI and POP. The Nilsson study used an older cohort of women, the oldest being 87 when implanted with a TVT. Using older women with inactive sex lives is unlikely to reveal dyspareunia and loss of sex life.

https://slingthemesh.files.wordpress.com/2018/06/17-years-follow-up-2.pdf

https://www.ethicon.com/na/products/uterine-and-vaginal-surgery/incontinence-slings/gynecare-tvt-retropubic-system-tension-free-support-incontinence

2.1.7 Professor Carl Heneghan, Director of the Centre for Evidence-Based Medicine, University of Oxford, summarised the four publications of the above Nilsson trial with 5, 7, 11 and 17 years of follow-up, as follows:

**2005 publication (Five-year follow-up first published as a supplement in 2001):** The study population consisted of 90 consecutive patients who were enrolled in a prospective multicenter trial in three Nordic centres between 1st January 1995 and 15th October 1996. Of these 90 women, 85 (%) could be evaluated after five years according to the protocol (five had to be interviewed by phone) 72 of the 85 patients were assessed (85%) as cured; 9 patients (10.6%) were significantly improved and 4 (4.7%) were regarded as failures.

**2007 publication (Seven-year follow up):** The study population consisted of the same 90 women, but now only 80 (89%) were followed up: 3 had died, 6 lived in nursing homes, being

disabled to the degree that they could not be evaluated, and 1 woman was completely lost to follow-up. You could have reported this result as 10% of women had died or been fatally disabled; but instead, objective and subjective cure rates were reported as 81%.

**2008 publication (Eleven Year follow up):** One year later the eleven-year follow-up was published with the same 90 women. Now only 69 (77 %) women could be assessed: 53 women were seen at the clinics and 16 contacted outside the clinics, and 77% (53/69) regarded themselves as cured.

**2013 (Seventeen years follow up):** The study consisted of the 90 women, but only 58 (64%) women could be invited to visit the clinics, and 46 women were assessed according to the clinical protocol. But, look what happens. Suddenly cure rates get better: 42 out of 46 women (91.3 %) stated they were cured. This is backed up in the abstract, which reports: 'Over 90 % of the women were objectively continent.'

**The shrinking denominator:** The shrinking denominator effect happens when you fail to include all of the patients in the analysis, an intention to treat (ITT) analysis would include all 90 women. In an ITT analysis, the results are based on all those initially assigned to the intervention and it leads to smaller effects because the denominator is often much larger than the group followed up. With all the data less than half of the women (42/90; 47%) would be cured.

https://blogs.bmj.com/bmjebmspotlight/2018/09/12/tvy-seventeen-year-follow-up-and-the-misleading-effect/

https://www.bmj.com/content/363/bmj.k4155

2.1.8 In this 2017 paper Prof. Heneghan states there is a crisis of confidence in the evidence base. "Informed decision making requires clinicians and patients to identify and integrate relevant evidence. But with the questionable integrity of much of today's evidence, the lack of research answering questions that matter to patients, and the lack of evidence to inform shared decision. how are they expected to do this? Too many research studies are poorly designed or executed. Too much of the resulting research evidence is withheld or disseminated piecemeal. As the volume of clinical research activity has grown, the quality of evidence has often worsened, which has compromised the ability of all health professionals to provide affordable, effective, high value care for patients."

https://www.bmj.com/content/357/bmj.j2973

## 2.2 Scientific evidence for pelvic mesh use for sacrocolpopexy and sacrohysteropexy

2.2.1 Patient experience on STM has shown us that abdominal mesh for vaginal prolapse - sacrocolpopexy and sacrohysteropexy – can sometimes result in the same grave complications as vaginally inserted prolapse mesh, which was effectively banned in December 2017 under interim NICE guidelines. Sacrocolpopexy is used for vaginal vault prolapse when

the vault of the vagina comes down after a hysterectomy. Sacrohysteropexy is for womb/uterine prolapse.

https://www.nice.org.uk/guidance/ipg583/resources/sacrocolpopexy-using-mesh-to-repair-vaginal-vault-prolapse-pdf-1899872166977989

https://www.nice.org.uk/guidance/ipg584/resources/uterine-suspension-using-mesh-including-sacrohysteropexy-to-repair-uterine-prolapse-pdf-1899872168657605

2.2.2 Patient experience reveals many women in the group who received these abdominal meshes for vaginal prolapse were not warned of any serious complications. They were assured it was an easy, low risk procedure. In some cases they are suffering serious, life altering debilitating pain, infection and loss of sex life. Scottish woman Eileen Baxter, who died in August 2018, had sacrocolpopexy mesh. Multiple organ failure and sepsis was cited as the primary cause of death on Mrs Baxter's death certificate, with "sacrocolpopexy mesh repair" named as an underlying factor. The Scottish Government has called for an enquiry following her death. This shows abdominal prolapse mesh is capable of extreme harm. A Scottish Government has put this mesh under strict governance. https://www.bbc.co.uk/news/uk-scotland-edinburgh-east-fife-45430625

2.2.3 STM has a significant number of members who have been seriously injured by vaginal abdominal prolapse mesh. A recent STM September 2018 survey of members (see Annex 15) shows that 3 per cent had a sacrohysteropexy and 4 per cent had a sacrocolpopexy, giving a total of 7 per cent. This compares to 11 per cent who received transvaginally inserted prolapse mesh.

2.2.4 STM is concerned that the studies used to make decisions about abdominal POP operations have the same underlying issues of inadequate outcome measures to record the long term complications such as pain, voiding dysfunction, infection and dyspareunia. A woman could present in extreme pain but many of the outcome surveys would not capture this information because if her original problem is fixed she would show up in trial paperwork as a success. There will also be the same theme of some trial authors receiving funding from industry which introduces a risk of bias.

2.2.5 2.2.5 There fewer studies on sacrohysteropexy than on sacrocolpopexy – certainly not enough to give a strong evidence base for use.

2.2.6 The NICE guidelines of 2017 for both procedures state they are under "standard" arrangements which are not strong enough. The guidance says "current evidence shows that for both of these operations: "There are serious and well recognised complications. The evidence on efficacy is adequate in quantity and quality. Therefore, this procedure can be

used provided that standard arrangements are in place for clinical governance, consent and audit."

2.2.7 The new draft NICE guidelines on pelvic organ prolapse do not make any additional changes to this advice. Therefore, STM does not believe these guidelines are strong enough to protect women. Abdominal prolapse mesh has been recommended for standard arrangements when it should always have been special arrangements. Standard arrangements are described by NICE as: "Our most positive recommendation. It means that there is enough evidence for doctors to consider this procedure as an option." Yet even by NICE's admission these transabdominal vaginal mesh types can have serious complications- so should be under special arrangements. This is for when: "There are known risks of serious harm that need to be carefully explained to the patient before they make a decision. It emphasises the need for informed consent, both from the patient (or carer) and from senior medical staff, such as the clinical governance lead in their trust. Clinicians using the procedure should also collect data, for example by audit or research. If there is no method of data collection already available for a procedure, we publish an audit tool alongside the guidance."

https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/interventional-procedures-guidance/recommendations

2.2.8 The 2017 NICE review of sacrocolpopexy noted that "registry data collection has been disappointing". If these types of surgery are going to continue the full ranges of outcomes should be logged using Patient Recorded Outcome Measures (PROMS). This must be done using a mandatory national database and/or a full national recall as the latter is the only way to get a true picture of the scale of suffering.

## 2.3 Scientific evidence for pelvic mesh use for ventral rectopexy

2.3.1 In recent years the use of ventral mesh rectopexy (VMR) has risen. It does not seem to have been used as extensively in other countries as it has been in the UK. The spread of the ventral mesh rectopexy operation as the preferred procedure for rectal prolapse may be concerning given the fact that there are alternative options without the use of mesh used elsewhere. There are more limited studies on VMR compared to vaginal POP or SUI mesh. Study results typically quote low complication rates.

2.3.2 STM is concerned at the severity of ventral mesh rectopexy complications seen amongst support group members. A recent September 2018 STM survey found that 7% of respondents have been injured by ventral rectopexy (see Annex 15, Fig 1.) It is not possible to tell how many patients have had VMR because there is not a specific hospital code for it, but it would appear that VMR has been a much less frequently performed procedure than TVT mesh for SUI.

2.3.3 STM has members with significant complications from VMR such as chronic pain and loss of sex life. In addition many have even been fitted with colostomies or ileostomies due to mesh complications or loss of bowel function, and have hospital visits suffering complications arising from this. Patient experience shows us women suffer can severe bowel complications after this type of mesh. A high number of the VMR patients on STM refer to having undergone or being suggested to undergo further surgeries after LVMR. These surgeries include but are not limited to: STARR procedures, Delorme's procedures, SNS procedures, stoma procedures, further redo rectopexies- in some cases more than 3 have been reported within a short timeframe. Rectopexy mesh was cited as factor in the suicide of Welsh woman Lucinda Methuen Campbell in January, showing the devastating effects of VMR on some patients. Mrs Campbell hung herself when she could no longer with the physical pain and emotional suffering caused by her rectopexy and also the removal of her ovaries during the VMR operation.

https://www.telegraph.co.uk/news/2018/05/29/woman-killed-surgeon-removed-ovaries-operation-getting-way-inquest/

2.3.4 Again, as with other mesh types, many of the studies used to assess the procedure do not appear to have robust enough outcome measures to record the short and long term complications described above. For this reason STM believes that the recent NICE review is not strong enough to assess the risks of this procedure. NICE guidelines state that VMR should be subject to special arrangements but STM say this is not sufficient. In addition, the recently published draft NICE guidelines for mesh excludes ventral mesh rectopexy in the proposed national database- this is a significant omission. VMR is an abdominal POP mesh.

https://www.nice.org.uk/guidance/ipg618/resources/laparoscopic-ventral-mesh-rectopexy-for-internal-rectal-prolapse-pdf-1899873928895173

https://www.nice.org.uk/guidance/indevelopment/gid-ng10035/consultation/html-content-2

2.3.5 A current trial on ventral rectopexy appears to have improved outcome measures, but there may be an ethical argument against implanting further patients with mesh when one could gather similar data by conducting a national mesh recall and avoid harming new patients. The trial is called Capacity-03. https://www.qmul.ac.uk/pctu/about-us/clinical-strengths-and-studies/our-studies/capacity/

## 2.4 The need for unbiased scientific evidence for mesh use

2.4.1 STM understands the root cause of the mesh scandal is the vast underreporting of complications caused by mesh device implants. Much of the scientific literature is heavily influenced by industry. Scientific evidence is rightly used to underlie key decisions, but there

is a major concern that much of the medical scientific literature has become corrupted and therefore inaccurate. Manufacturers and pro-mesh surgeons cherry pick studies to indicate mesh devices are low risk, while it is left to campaigners to highlight the flaws in these studies and to highlight other studies that indicate it is anything but low risk, (for example the heavy reliance on the flawed Nilsson study discussed in 2.1.5 and 2.1.6 above.)

2.4.2 Even when a study reports high complication rates, the conclusion is that mesh is an effective treatment option for the 'majority' of women. So for busy readers, scanning to the conclusion, they will assume all is well. One example already mentioned is the TOMUS Study that revealed out of 597 women, 42 per cent suffered an adverse event from a mesh sling for incontinence, of these 20 per cent were classed as serious. Despite this, the conclusion says that although adverse events are common after midurethral sling, most events do not cause significant long-term problems. Yet there is a severe lack of unbiased data on long-term problems. Another significant issue is that many Randomised Controlled trials (RCTs) often compare one type of mesh to another as opposed to mesh vs. a natural tissue repair; so no meaningful conclusions are made about the safety of mesh. Most RCTs also contain small cohorts, contain differing sets of core outcomes and only follow up trial patients for a limited period of time.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3205289/

2.4.3 A case in point is a 2005 study published in BJOG funded by GyneaCare, which used data from GyneaCare's international manufacturers log of complications. In its conclusion, the TVT is described as an acceptable surgical treatment for stress incontinence, despite the following findings, which state the safety of the TVT had not been proven before implantation into women:

- "It is difficult to ascertain accurate rates of complications from the literature… therefore, many complications remain unreported."
- "More information on the specific clinical issues presented in this review, the tissue reaction around the tape and the management of complications are awaited. However, large, randomised studies with follow up to five years are required to firmly establish the TVT as a safe, effective, long term remedy for stress incontinence, ensuring that it does not fall into the same disrepute as anterior repairs or needle suspensions. "
- "Much of the data are from non-peer-reviewed small case series often 'published' as abstracts. As a result, the conclusions should be interpreted cautiously."
- "The results of these early case series should be viewed with caution as observational studies without a comparison group risk bias."
- "The first fully reported trials came in 2002 showing TVT cure rates equal to laparoscopic and open colposuspension. Two were quasi-randomised, risking selection bias, with only one fully randomised controlled trial (RCT)."
- "These longer-term results are observational and should be viewed with caution until randomised, comparative data are available."
- The majority of compartive data "are 'published abstracts' and should be interpreted cautiously as the data are preliminary with small numbers and short follow up."
- In the elderly, "Theoretically, this might increase the risk of failure, post-operative overactive bladder, tape erosion, retention and bladder perforation. Currently, there are few data to specifically assess these issues, despite the

many studies that include elderly women. The impact of age on various outcome parameters requires further assessment."

- There is a paucity of studies on sexual function.
- "The significance for long term voiding difficulties remains unknown."
- There "might be true tape migration."

https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/j.1471-0528.2004.00498.x

2.4.4. STM is concerned about a current study that is planned for implementation in 10 research centres across the UK, based in Norwich, and designed to evaluate the safety and efficacy of low elasticity polyvinylidene fluoride (DynaMesh®-SIS soft) retropubic tension-free midurethral slings in the treatment of stress urinary incontinence (SUI) in women. It is a short-term one year clinical follow up trial followed by postal questionnaires for one year. The trial states it is being conducted because the use of permanent polypropylene mesh in gynaecology has come under scrutiny due to significant complications for women. The trial documents state that compared to conventional polypropylene mesh, DynaMesh®-SIS has a reduced reactive surface area. Given its physical properties the exposure and erosion rate of DynaMesh®SIS soft sling are not thought to be greater than that of traditional polypropylene slings. The trial will assess subjective cure rate in treating SUI and the rate of complications, particularly vaginal erosions. STM has grave concerns about lack of informed consent, and the use of validated Quality of Life questionnaires that focus solely on incontinence as well as the short timescale of the trial. The research protocol document states that research consent will consist of the study being explained to the patient while ensuring the patient's study related questions are answered. Given past history of incentives given to doctors recruiting high numbers of trial patients, STM is concerned that fully informed consent may be compromised if all the risks are not communicated, including erosion into organs and vaginal wall, chronic pain and dyspareunia – all of which will be evaluated in this trial for a very short time. The controversial SIMS trial is an example of unacceptable incentives given to trial doctors.

https://www.dailyrecord.co.uk/news/scottish-news/mesh-surgery-scandal-fury-doctor-4762910

2.4.5 The Health Technology Assessment of tension free vaginal tape, 2003, recommended further research should include unbiased assessments of longer term performance from follow-up of controlled trials or population-based registries; more data from methodologically sound RCTs using standard outcome measures; a surveillance system to detect longer term complications, if any, associated with the use of tape; and rigorous evaluation before extending the use of TVT to women who are currently managed non-surgically. There is an urgent need for unbiased trials of more than five years on the safety of TVT (tension free vaginal tape).

2.4.6 Studies on the safety of pelvic mesh have largely been limited to small cohort sizes, short-term duration and often biased, resulting in low complication rates. Studies average one-two years duration, yet multiple mesh complications often occur years after mesh

insertion. In addition, poor Quality of Life questionnaires used in studies do not identify complications of mesh. This is due to questions focused solely on whether mesh has cured the urinary incontinence problem, while omitting questions on whether the mesh itself is safe and has caused other health problems. If science does not ask the questions it does not get the answers. Therefore, it is essential for the Review to address the issue of short term flawed or biased research. This is needed given that decisions on continued mesh device use always refer to the 'evidence', which is more often than not false, flawed or incomplete. If the data presented in scientific papers were accurate, reflecting a good representative snapshot, this would enable patients to be correctly informed of risk and benefit. There is no longitudinal study that shows the true scale of mesh device complication rates due to poor Quality of Life questionnaires restricted to incontinence and the short term duration of most of the research.

2.4.7 The concern over flawed scientific studies has been highlighted by Dr Richard Horton, Editor in Chief of The Lancet, who stated,

'*Much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness*.'

https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736%2815%2960696-1.pdf?code=lancet-site

Furthermore, the reputation of the prestigious scientific organisation, the Cochrane Collaboration, dedicated to independent reviews of health care interventions, is under threat due to concerns about it being compromised by commercial interests.

https://blogs.bmj.com/bmjebmspotlight/2018/09/16/cochrane-a-sinking-ship/

2.4.8 STM is aware that a permanent ban on the current mesh will lead to more clinical trials into prosthetic devices that aim to avoid the same adverse effects seen with the use of current meshes. STM believes that any future research, clinical trials and clinical audits need to encompass the omissions in research protocols outlined above and a minimum 'core outcome set' to avoid the issue of some studies only reporting a selection of the outcomes that were measured. If all studies contained the same core minimum outcomes they could be compared, contrasted and combined. This would provide more robust and consistent evidence across trials and reduce selective reporting of outcomes. Patients and support groups should also be included in the design of core outcome sets.

http://compare-trials.org

http://www.comet-initiative.org

2.4.9 STM calls for the Review to undertake an independent assessment into STM's concerns about omissions in research protocols (particularly informed consent, QOL questionnaires that focus on SUI with mesh risks downplayed or omitted) for past, current and future pelvic mesh trials in the UK and a suspension of all current and planned trials for any type of pelvic mesh until the outcome of the Review.

## 2.5 History of ignoring the science of polypropylene mesh, and evidence that polypropylene mesh is cause of complications

2.5.1 If the forthcoming Review is to stand up to scrutiny then STM strongly recommends that the science of polypropylene mesh devices, and assessment of effects in the body over time must be evaluated in the Review. While other mesh substances are in use it is this polymer which has been implanted in the majority of women with pelvic mesh devices and STM believes that questions over safety needs to be addressed. Concerns have repeatedly been raised about the safety of polypropylene and the regulatory process used to assess its use in the pelvis. The recent NHS England review did not look at this issue in any meaningful way. Jeremy Hunt stated on 21 February 2018 that the forthcoming Review is not going to 'revisit' the science of polypropylene mesh. STM would like to see the evidence that the science of mesh and its effects in the human body was ever visited in the UK in the first place.

https://hansard.parliament.uk/Commons/2018-02-21/debates/7DA2E2F3-E1E6-40CB-8061-680E0399CA97/MedicinesAndMedicalDevicesSafetyReview

2.5.2 Junior Health Minister, Jackie Doyle-Price, stated in a Westminster debate on vaginal mesh in October 2017, that the issues with mesh were related to clinical practice and not to the devices themselves. These statements have led STM to conclude the safety concerns attributed to the polypropylene material used in these devices and the changing architecture of mesh material in the body - that causes significant injuries – have been deliberately ignored over the past 20 years

2.5.3 Scientific research findings are constantly evolving. If the science ever was 'visited' when polypropylene mesh medical devices were introduced in the 1990s, the science has moved on since then. One example is the introduction of coatings on pelvic mesh in an unsuccessful attempt to prevent inflammatory reactions of older mesh products, which were withdrawn. This is evidence that manufacturers were aware of problems with mesh that remains implanted in hundreds of thousands of women worldwide.

2.5.4 The science of polypropylene mesh has been ignored for too long including oxidative degradation occurring in vivo. This is clearly illustrated in the Ostergard article mentioned in paragraph 2.5.14 below. Given the evidence, the science research needs to be addressed urgently, along with the focus on improving clinical practice, systems and processes. There is

a strong moral argument, if not an ethical one, that the science of polypropylene mesh should be proved safe. We know that the influence of the medical device industry has contributed to this lack of focus. The Review needs to establish whether polypropylene mesh itself is harmful to humans, immediately after implantation and over time. Furthermore, it is critical to assess whether the harm reported by women concurs with the scientific papers published regarding the degradation of polypropylene mesh material and its coatings in vivo, and the resultant effects on the human body.

2.5.5 STM believes there has been a history of institutional denial concerning the safety of polypropylene mesh. In May 1996, the Academy of Medical Royal Colleges (AOMRC) established the Committee on the Safety and Efficacy Register of New Interventional Procedures (SERNIP). A Clinical Director was appointed. SERNIP became the responsibility of the Department of Health on 1 December 2001. The functions of SERNIP were then taken over by the NICE programmes on interventional procedures and then the MHRA.

2.5.6 The TVT mesh device procedure was considered in 1997 by SERNIP and was considered to be safe and effective based on a short- term case study by Ulmsten who introduced the technique. There was heavy promotion by the production company. There were no long-term studies. SERNIP was, however, warned that coated polypropylene mesh may undergo degradation in vivo but the committee ignored this. Dr Vincent Argent, O&G surgeon, shared with STM that in 1997, the Advisory Committee of SERNIP considered the available data on TVT mesh and gave the procedure category 'A' which indicated 'Safety and efficacy established: the procedure may be used.' NICE adopted this recommendation on takeover from SERNIP. The SERNIP procedures were superficial and subject to considerable peer group pressure to approve unproven procedures. In his role as NICE Women and Children's Health Guideline Review Group member, Dr Argent has stated that,

*"I strongly advised SERNIP and then NICE that there were very few studies of early and long term outcomes and that anti-oxidant coated polypropylene mesh would cause major tissue reaction. I told SERNIP that the reliance on the predicate 'substantial equivalence' approach by Notified Bodies was very high risk. I repeated my advice during the drafting of the NICE Urinary Incontinence Guidelines in 2003 and the NICE Guidelines on Consent where the benefits and risks are uncertain in 2003. My comments were overruled by some powerful urogynaecologist colleagues who considered my approach to be compromising safety by not making use of the mesh implants*." (Vincent Argent, June 2018)

Other medics have voiced their concern about SERNIP's effectiveness in a recent BMJ article: https://www.bmj.com/content/363/bmj.k4137

2.5.7 In 2016, in The People of the State of California V Johnson & Johnson; Ethicon Inc 2016, the State also raised concerns about the Ulmsten study as follows: -

"J&J knowingly cited to studies for which results were scientifically questionable due to study design and/or conflicts of interest. For example, J&J used the result of the Ulmsten study to sell its SUI products when J&J had (1) purchased the rights to the SUI device from Dr. Ulmsten and (2) contractually agreed with Dr. Ulmsten that he would only get paid a specific sum if his study produced favourable results regarding the product."

https://oag.ca.gov/system/files/attachments/press_releases/J%26J%20Complaint_1.pdf

2.5.8 A 2003 BMJ article points out that SERNIP had limited NHS funding and was entirely voluntary and had a limited profile and impact. In general, SERNIP procedures were reportedly not robust and lacked scientific rigour.

https://www.bmj.com/content/326/7385/347

2.5.9 The work of SERNIP was then taken over by the Medical Devices Agency (MDA), and then NICE. The subsequent NICE publications on SUI surgery and TVT did mention the lack of research about long-term outcomes. STM believes the Review should look at the early days of SERNIP and its significant limitations as the UK moves towards the implementation of the EU MDR 745 Regulations on Medical Devices.

2.5.10 The majority of pelvic mesh complications and injuries are reported to be a direct result of the changing architecture of polypropylene mesh implants due to chemical interactions in the body. The implications of oxidation and degradation of polypropylene transvaginal mesh have been published in numerous peer reviewed articles in scientific journals (see References.). Research stating oxidation and degradation is a myth was written by conflicted authors (see list of references.) Examples of evidence of oxidation and degradation of polypropylene in the human body are as follows:

https://slingthemesh.files.wordpress.com/2018/05/phantom-plastics-mostyn-law-pp-mesh-design-report-final-cd-2018.pdf

https://www.parliament.nz/resource/en-NZ/51SCHE_EVI_50DBHOH_PET3197_1_A433873/ba67c0e7e5f20015d86ec5ed67fb7f8e1a5117c5

2.5.11 In 1997, mesh implant manufacturers were told not to use 'Marlex' polypropylene resin in the creation of mesh products intended for use in the human body. In January 2004, the producers of Marlex (Chevron Phillips) wrote formal warning notices to mesh manufacturers:

'Medical Application Caution: Do not use this material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from

Chevron Phillips Chemical Company LP or its legal affiliates under an agreement, which expressly acknowledges the contemplated use. Chevron Phillips Chemical Company LP and its legal affiliates makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for use in implantation in the human body or in contact with internal body fluids or tissues.'

Mesh manufacturers however, continued to use this polypropylene resin. According to a 2018 CBS documentary, Boston Scientific, for example, began to purchase this resin through third party suppliers and failed to tell the suppliers that the resin would be used for medical device implants. Following concerns that the "Marlex" product sourced in China may be counterfeit, Boston Scientific continued to use the material in their pelvic mesh products. There have been allegations that such mesh products were implanted in Scottish pelvic mesh patients. The FDA has declared this mesh to be safe, but the controversy continues.

https://www.cbsnews.com/news/boston-scientific-gynecological-mesh-the-medical-device-that-has-100000-women-suing/

https://www.dailyrecord.co.uk/news/scottish-news/mesh-8859881

https://www.sundaypost.com/fp/memos-reveal-mesh-firms-were-warned-21-years-ago-that-material-should-not-be-used-on-humans/#r3z-addoor

https://www.meshmedicaldevicenewsdesk.com/mesh-101-basics/

https://www.sundaypost.com/fp/surgeons-and-politicians-call-for-immediate-ban-of-mesh-implants-made-with-chinese-plastic/?utm_source=twitter

2.5.12 An article by Ostergard in 2011 article states, 'There has been a lack of dissemination of information regarding many of the characteristics of polypropylene mesh especially the many factors which are implicated in the complications that patients experience postoperatively." Ostergard lists numerous research studies that show:

- As soon as mesh is implanted bacteria and host defence cells race to the mesh surface
- Bacteria migrate alongside the synthetic fibres
- Polypropylene mesh shrinks 30-50 per cent after four weeks
- Bacterial colonization was found in 33 per cent of mesh that had been removed
- The abdominal wall stiffens after mesh is implanted
- Mesh surface predicts bacterial adherence – multifilament mesh has a 205 per cent increase in surface area which may explain infections up to years after device implanted
- Degradation occurs in all meshes.

http://paperity.org/p/11116169/degradation-infection-and-heat-effects-on-polypropylene-mesh-for-vaginal-implantation-what

**Box 1: Polypropylene is not inert within the human body**

'The vagina is a clean-contaminated environment, and it is not possible to insert polypropylene mesh devices without bacterial contamination, despite standard antibiotic usage. Once inserted, the host tissue immediately attaches to the polypropylene and attempts to defend it from bacterial invasion, but if the bacteria have already reached the surface of the device, then dislodgement is difficult. The devices with larger surface areas result in greater bacterial contamination, more polypropylene degradation, increased inflammatory response, fibrous tissue stimulation, and erosion. Non inert polypropylene degrades into potentially toxic compounds that would be expected to stimulate a greater inflammatory reaction leading to erosion. If the physician does not place the mesh below full-thickness vaginal epithelium, penetrates the epithelium during insertion, or if there is hematoma formation near the vaginal incision, then defective healing and erosion may result. Scar tissue causes contraction to less than 50 per cent of the implanted size, which results in dyspareunia and tension on the vaginal mesh attachments. Such contraction may cause vaginal pain and subsequent erosion into adjacent organs. An individual response in fibrosis also exists, with some individuals being "high responders."

https://www.researchgate.ne't/publication/46393542_Polypropylene_vaginal_Mesh_Grafts_in_Gynecology

2.5.13 Foreign body reaction to biomaterial is highlighted in the findings of numerous studies that suggest that the two major mesh complications (exposure and pain) are associated with a marked pro-inflammatory response that persists years after mesh implantation**.** See References for detailed list.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5201165/

http://ec.europa.eu/health/scientific_committees/emerging/docs/surgical_co_christensen.pdf

2.5.14 It is also interesting to note that polypropylene has been mentioned as an irritant in sanitary products. Dr Nunns, consultant gynaecologist at Nottingham City Hospital, recommends his patients change to all-cotton sanitary products because the skin of the vulva is the most sensitive on a woman's body and easily irritated by polypropylene, perfume and bleach, common ingredients in sanitary ranges. He says: "All too often, women are sent away with a prescription for Canesten or whatever, as thrush is the easiest thing for a GP to diagnose. They don't have the time or inclination to think beyond that. Most patients report that they aren't even examined."

https://www.theguardian.com/world/2003/nov/07/gender.uk

2.5.15 A 2017 STM survey revealed that 25 per cent of respondents reported development of autoimmune disease after mesh insertion (Annex 2). Various conditions including lupus, Sjogren's syndrome and polymyalgia rheumatica have been reported by STM members. There have been few studies linking autoimmune disease and polypropylene mesh, however this is beginning to change. In 2018 Professor Jan Cohen Tervaert reported this link when he spoke at the 11th International Conference on Autoimmunity in Lisbon. He reported the findings of a study in 40 patients with mesh who developed symptoms such as chronic fatigue, cognitive impairment (also known as 'brain fog'), muscle and joint pain (fibromyalgia), rashes, feverish temperature, and dry eyes and dry mouth. Significantly, 45 per cent of the patients developed an autoimmune disease. Polypropylene mesh is known to act in animal models as an adjuvant that accelerates or enhances an immune response. According to Professor Tervaert, if a person has a genetic pre disposition to develop an autoimmune disease then an implant like mesh will increase the risk.

http://ec.europa.eu/health/scientific_committees/emerging/docs/surgical_co_hardacre3.pdf

2.5.16 Professor Cohen Tervaert believes large-scale studies are needed into the link between mesh and the development of autoimmune disease. "These symptoms are probably not coincidental because we also see other symptoms of adjuvant disease, which is the occurrence of well-defined autoimmune diseases, which I found in my population in 45%, and finally also immunodeficiency." (See link)

https://www.meshmedicaldevicenewsdesk.com/mesh-autoimmunity-allergies-and-vitamin-d/

https://www.folio.ca/surgical-mesh-implants-may-cause-autoimmune-disorders/

https://www.netflix.com/gb/title/80170862

http://meshproblems.weebly.com/linking-the-research-from-fbr-to-implant-materials-to-autoimmune-disease-initiation-or-exacerbation.html

http://www.washingtonpost.com/wp-dyn/content/article/2008/04/15/AR2008041502161.html

2.5.17 A member of STM was directed by her consultant, to an article in the International Journal of Clinical Medicine (2014) when discussing her pelvic mesh complications 'Surreptitious Irreversible Neuralgia (SIN) caused by polypropylene mesh' which states, "It is surreptitious because it is of slow onset, unsuspected and enigmatic to clinicians; irreversible because the pain is progressive, unrelenting and unresponsive to treatment. Removal of the

mesh does not guarantee pain relief." The article explains that, "vasculature, nerves and their receptors are exposed to potential mechanical and chemical factors: scarring, entrapment, compression, tugging, deformation, contraction, hypoxia/acidosis, inflammation and edema". Most of their explanted samples showed a giant cell inflammatory reaction.

http://file.scirp.org/pdf/IJCM_2014072117033945.pdf

2.5.18 A key conclusion of the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) review into the safety of the use of transvaginal mesh in urogynaecological surgery, 2015, is that 'in assessing the risk associated with mesh application, it is important to consider the overall surface area of material used, the product design *and the properties of the material used.'* SCENIHR's recommendations include:

• '*Material properties*, product design, overall mesh size, route of implantation, patient characteristics, associated procedures (e.g. hysterectomy) and surgeon's experience are aspects to consider when choosing appropriate therapy.'

https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_27_en

2.5.19 The 2015 SENIHR study commented that findings on experiments conducted on sheep revealed the mesh stiffened within 90 days. The report cites numerous studies on animals (sheep, rabbits, pigs, rats) from 2002 – 2013 in which chronic inflammation was found from day 1 of implantation to the last 3 month follow up. Fibrosis was also found at the 3 month follow up. Numerous human studies were cited from 2004 – 2012, in which it was found "polypropylene meshes were invaded with macrophages and leukocytes, inflammatory infiltrates and collagen production… In summary, polypropylene meshes provoke pronounced inflammation, leading to a massive cell infiltration into the scaffold and ultimately induce collagen production."

2.5.20 Given the above information, STM believes key questions remain unanswered as follows:

i. If this was occurring in animals before the mesh was implanted in humans and the same complications subsequently occurred in humans, and these findings were available from 2002 until 2013 - why has it taken so long for women's complaints about mesh complications to be acknowledged?
ii. Have any of SCENHIR's 2015 recommendations, as listed below, been implemented? And if not, why not?

- Ensure that patients are correctly and comprehensively informed relating to the performance and risks associated with synthetic non-absorbable meshes
- Establish European implant registries
- Establish scientific studies to assess the long-term (at least 5 years) safety and performance of synthetic non-absorbable meshes

- Adopt evidence based Pan-European Guidelines
- Develop training programs for surgeons in association with European medical associations

http://ec.europa.eu/health/scientific_committees/emerging/docs/surgical_co_eau3.pdf

2.5.21 STM argues that literature reviews of mesh complications have limited value given that many report authors conclude that more research needs to be done and long-term follow up of patients is required to monitor and evaluate complications. The role of polypropylene degradation in the development of complications has not been studied extensively. This is surprising given the main source of information, the explanted pathology specimens from patients with mesh complications, have not been given appropriate attention. Scientists who have conducted studies on explanted mesh have shown that a focused examination of explanted material reveals features indicating polypropylene degradation in the body over time that has been overlooked for decades.

**Box 2: What is a Medical Grade Polymer?**

An article in Medical Plastics News highlights the ambiguity of the definition of 'What is a Medical Grade Polymer?' (Bastiansen S, Medical Plastics News, Issue 42, May-June 2018, p 43-45 )

*'Despite strict international and national regulations as well as demanding requirements for medical polymers, one extra difficulty in this choice is the fact that there has been no universally accepted definition of ' medical-grade ' polymers…The industry has yet to answer one seemingly simple question - What is 'medical-grade ' polymer.*' The author goes on to point out that ' *The new European Medical Device Regulation 2017/745 (MDR), which will be mandatory from 26th May 2020, places a strong emphasis on risk management and safety*.'

https://www.eppm.com/materials/the-medical-grade-polymer-dilemma/

2.5.22 STM assumes the MHRA will comply with the new EU medical device regulation 745 despite Brexit. The article highlighted in Box 2 is very important information for the Review team to consider, as well as its implications.

2.5.23 According to HES statistics 126,000 women in England in a 12 year period alone have been implanted with pelvic mesh in NHS hospitals. Even a 10 per cent complication rate (which is very likely to be an underestimate due to underreporting) means 12,600 women have been affected. A 30 per cent rate would mean close to 40,000 women. What is not known, due to a vast lack of monitoring data over the past 20 years, is how many women are and will be

affected by a pelvic mesh implant as it can take years after implantation before complications arise. The science of polypropylene mesh has been ignored for too long including oxidative degradation occurring in vivo.

2.5.24 In order for the forthcoming review to consider how the health system responds to reports from patients about side effects from treatments, whether any further action is needed relating to the complaints around pelvic mesh and the processes followed by the NHS and its regulators when patients report a problem - then the robust evidence on the science of polypropylene mesh in the human body (not funded by industry) must be evaluated. The Review must also address the issue of mesh complications as a direct consequence of polypropylene degradation being wildly underreported and ignored. STM's view is this has been a major factor in not getting to the truth concerning mesh related injuries.

## 2.6 Questions on the use of biological mesh grafts as an alternative to synthetic mesh

2.6.1 Action called for by STM in this report applies equally to biological mesh. Biological meshes are grafts made of porcine or bovine collagen which vary in their nature and make-up. Serious complications have been reported following the use of these devices by members of STM. None of these meshes were designed to be removed if and when complications arise.

2.6.2 The large PROSPECT study looked at more than 3,000 women with vaginal prolapse. The study separately compared mesh and biological grafts to a standard native tissue repair without these additions. The study indicated that synthetic meshes and biological grafts materials give no additional benefit, with additional adverse effects and yet cost more. Whilst this study looked at outcomes for transvaginal prolapse repair, comparisons of the material used for the repair are still likely to have relevance to the use of biological mesh in other prolapse surgeries.

The PROSPECT trial findings were stated as being:

- One year after *primary* surgery, prolapse symptoms were no better in women who had mesh compared with women who had a standard surgical repair
- Similarly, the improvement in symptoms at one year was no better in women who had biological graft repair than in women who had a standard repair
- Compared with standard repair, using a synthetic mesh cost an additional £363 per woman and biological graft an extra £565.

2.6.3 Biological grafts have been reported with a higher anatomic failure rate for prolapse compared to synthetic mesh, hence why synthetic mesh has been widely used. The Cochrane review found insufficient evidence to compare biological grafts with standard native tissue repair. Unfortunately due to poor HES coding there is little in the way of evidence of how many women have been suffering from

biological mesh grafts. There is no specific biological mesh HES code. However, the more recent PROSPECT study found that women with biological mesh grafts two years post transvaginal prolapse repair (materials included porcine acellular collagen matrix, porcine small intestinal submucosa, or bovine dermal grafts,) were significantly more likely to report complications related to grafts as a support mechanism than women with standard native tissue repair.

2.6.3 STM patient experience shows women can suffer serious and debilitating pain as well a number of other problems such as autoimmune disease as a result of biological mesh implantation. Figure 3, Annex 15, show that 4% of STM member have biological mesh but this cannot be put into context without knowledge of how often this graft is used.

2.6.4 The PROSEPCT study defined serious adverse effects included infection, urinary retention, dyspareunia and other pain, and excluded specifically defined "mesh" complications as a serious adverse event. One year follow up data still revealed for biological graft 10 per cent of women suffered serious adverse effects compared to 6 per cent for standard repair procedure.

2.6.5 In STM's view the findings of the PROSPECT study highlights the need to consider more standard native tissue repairs in place of mesh or grafts in pelvic floor surgery, thereby eliminating the additional safety risks of mesh and biological grafts as a supportive mechanism. This may imply the need for more surgeons to be trained in standard repairs. If biological mesh grafts are to be considered as a standard replacement option to mesh, database - to log patients for life so that history of the mesh scandal does not repeat itself.

https://www.nice.org.uk/guidance/ipg599/documents/overview
https://discover.dc.nihr.ac.uk/content/signal-000464/using-mesh-does-not-improve-results-in-vaginal-prolapse-surgery

## Box 3: Testimony from STM members with Biomesh

**Patient 1**

**"**My only motivation is that women are informed before they have this surgery. Especially biomesh which women are told is 100% safe. I was told this and the published papers are very reassuring. I later saw a colorectal surgeon who is an expert in this field (….) who told me he thought it wasn't safe. So clearly some surgeons are aware or suspicious. I am a physician, not a surgeon in case anyone is worried; I have had 8 ops in 2 years and still have chronic pain as well as an ileostomy for life."

**"**They call the mesh 'dissolvable' but it doesn't dissolve. Rather because it is made of pig collagen it gets removed by the body's normal immune cells and replaced by scar tissue in it's place, meaning the healed wound should be stronger. If you have external rectal prolapse then you need something done and I would pick the procedure over a posterior resection rectopexy or a polypropylene mesh rectopexy but it is sold as a 'risk free' option and I had really bad complications. Surgeon said he hadn't seen it before.."

**Patient 2**

"After having my synthetic mesh removed, and replaced with a permacol biomesh, all my symptoms have worsened. I suffer extreme fatigue, hot and cold sweats, unable to control my temperature, sore throat, swollen glands, tinnitus, muscle and joint pain, dry eyes, dry mouth, lower back pain, severe pain in my abdomen, sex is too painful, pins and needles in my limbs. However, since the new mesh I have also developed recurring sinusitis, debilitating headaches, an irritating skin rash and an infected fluid that leaks from my belly button. Plus, the pain in my abdomen is now unbearable, it feels like it is going to explode"

**Patient 3**

"I had rectoplexy in 2003 had great trouble and pain after couldn't open my bowel following surgery. I had puss and blood from rectum, Was using enemas and irrigation with little effect. I had to have an ileostomy . I developed what is thought to have been ulcerative colitis in rectum and was constantly passing blood and pus terrible pain .I ended up having rectum removed in 2007 colpopexy and vaginal repair as the rectoplexy had failed with the first mesh . I continually complained of pain and they looked for every possible cause except mesh and I ended up extremely emotionally unwell."

**Patient 4**

**"**Great article by Woman and Home, but once again the emphasis is placed solely on plastic mesh with no mention of biological mesh. I get so despondent when only plastic mesh is highlighted when all mesh is bad. So many of us with biological mesh are suffering the same symptoms as pp. Biological mesh,i.e. pig and cow intestine causes the same devastating injuries as pp. It's a foreign body, it shrinks, it rots, it tears organs and nerves, it harbours bacteria and causes recurrent infections. I am on my eighth or ninth (I've lost count) of antibiotics and that's just the last 9 months. I've gone from having an active life to shuffling from bed to sofa. I've lost the life I once had and I miss it terribly. I've had a lung infection for the last eight weeks that antibiotics are not touching. If the current ones don't work, despite fighting against admission for the last six weeks, hospital is the only option. I'm in pain always, despite

## Action 3. Review of the structures and processes of mesh medical device regulation, approval and adverse affects reporting to enhance transparency and safety

### 3.1 Weak regulation of mesh devices

3.1.1 A significant problem lies with the governance of medical devices, in which regulatory failings have enabled new devices to be brought to market with inadequate evidence of their safety. It has long been known that the Medicines and Healthcare products Regulatory Agency (MHRA), has failed to adequately scrutinise data to ensure that the device meets the 'essential requirements' of health and safety, and its post-marketing surveillance has been inadequate for too long. This has several causes: the lack of effective post-marketing investigation of pelvic mesh device benefits and harms in real life situations, and institutional indifference to the experience and reports of those implanted with a pelvic mesh device. MHRA claims it does not have the funding to be able to properly oversee all medicines and devices now on the market.

3.1.2 Improvements to both regulatory approvals and the structures supporting evidence-based practice among clinicians are urgently needed to prevent similar problems in the future.

**Box 4**: Professor Carl Heneghan at Oxford University's Centre for Evidence-Based Medicine, who led research into vaginal mesh regulation, stated:

"*Many women have been subjected to great harm because regulatory loopholes allowed mesh devices to be made available in large numbers with no evidence in humans. It is now clear that regulation is not fit for purpose for the riskiest of devices, those that are implanted in the body.*"

*Refer to research:* BMJ 2017; 359 doi: https://doi.org/10.1136/bmj.j5515 (Published 07 December 2017)

3.1.3 In the US, vaginal meshes were initially class II devices, allowing them to be marketed on the basis of equivalence to existing devices. The study by Oxford University's Centre for Evidence-Based Medicine found 61 devices that were approved on equivalence claims and found there was no clinical-trial evidence for these devices at the time of approval.

3.1.4 The Oxford study found many of the devices were significantly different from the original device that had gained approval, with different materials, design and method of surgical implantation. Randomised clinical trials were found to be published an average of five years after device approval.

3.1.5 Prof Derek Alderson, the president of the Royal College of Surgeons, has recently said the benefits of surgical innovations must "absolutely, unequivocally" be backed by evidence, either through randomised controlled trials or official registries designed to track patient outcomes. The move would bring surgical innovation more closely in line with the way new drugs are introduced.

**Box 5**: Stephen Evans, professor of pharmaco epidemiology at the London School of Hygiene & Tropical Medicine, said:

"*The absence of good trials for these vaginal meshes, which has been investigated carefully by these authors [Oxford University December 2017 published study in BMJ], shows the problem clearly. Changes in regulation are often driven by lessons learned from very bad situations, such as thalidomide, and the need for change in regard to devices is clear."*

https://www.theguardian.com/society/2017/dec/06/woman-great-harm-due-loopholes-vaginal-mesh-regulation

https://www.theguardian.com/society/2018/jul/05/uks-top-surgeon-calls-new-procedures-undergo-clinical-trials

3.1.6 Robert Bendavid MD, University of Toronto & Shouldice Hospital, who designed two hernia mesh devices in 1986, wrote a letter to the Review team in July 2018, in which he states,

"The transfer of mesh knowledge to the urogynecologists, for their various applications, happened at a time when we began to notice that mesh had serious problems such as chronic pain, erosion into adjacent structures, infection, migration and degradation. The unfortunate transfer as everyone knows was done through the 510k clause of the FDA, a practice which should be condemned for many reasons. The pathology discovered in hernias is just as applicable in pelvic floor pathology and more so as one is dealing with a thinner, more delicate area of anatomy where erosion, bleeding, pain would become evident much sooner."

3.1.7 In 2006 Cardozo's editorial comment in the BJUI refers to the 3rd International Consultation on Incontinence, which took place in Monaco in 2004. Cardozo concluded that,

'transvaginal placement of permanent mesh …has an unacceptably high rate of complications that include erosion, infection, sepsis, dyspareunia and other functional symptoms. The risk of dyspareunia …is particularly worrying, as it is often under- reported… and the more recent mesh repairs, both being associated with an unacceptably high dyspareunia rate…. the

possibility that she may never be able to have satisfactorily penetrative sexual intercourse again needs to be fully explored. This balanced overview appropriately cautions us to remain judicious and withhold implantation of unproven mesh materials until manufacturers have confirmed their efficacy and safety.'

https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1464-410X.2006.06310.x

3.1.8 In 2007, Isom-Batz and Zimmern advised caution in the use of mesh. They reported high complication rates, for example, 38 per cent dysparenia, 18 per cent erosion for some types of mesh in only short term follow up and stated, "Even if the rates of these devastating complications are fairly low, they are life-changing for the patient, sometimes irreversible." They also quoted Donald Ostergard's concerns "that corporate 'engineering' takes the place of a physician's clinical judgment, knowledge of anatomy and potential complications in regards to the new 'kits' for prolapse and incontinence. He advised not to let industry control how we practice medicine: 'What industry is interested in is the fact that there are billions of dollars to be made from the sales of synthetic prolapse repair materials and the kits to perform the surgical procedure that accompany them'. He also questioned the current mechanism for FDA approval of new devices, given that this approval is only for the device and not for the surgical procedures efficacy or safety"

https://www.tandfonline.com/doi/pdf/10.1586/17434440.4.5.675?needAccess=true&

3.1.9 STM questions why, after 21 years of pelvic mesh device use and complications, no long term initiatives have been initiated to track devices in individual patients to gain a more complete picture of mesh complications. It is STM's understanding that the DHSC Scan4Safety programme that is now being piloted to address this tracking of devices will not be available to all Trusts until 2021. STM believes it is unacceptable that it will be another three years before monitoring begins and many more years of many more women being implanted with mesh devices before onset of complications. Women who have suffered from life changing complications feel strongly that no more women should be treated as 'guinea pigs' while the medical profession begins to belatedly respond to monitoring the mesh scandal.

3.1.10 STM would also like to draw the Review team's attention to the Netflix documentary released on 27/7/18 'The Bleeding Edge', in which employees of mesh manufacturers admitted that the harm mesh caused was known by mesh manufacturers *before* it was implanted into humans. The documentary also highlights the huge inadequacies in US regulatory systems, which led to medical devices being approved with no clinical trials and merely on the basis of equivalence.

https://www.netflix.com/gb/title/80170862)

3.1.11 See also, "One leaked email from Johnson & Johnson suggested it had known problems existed with one of its products since 2004. The email said the company needed to start a

"major damage control offensive" because "the competition will have a field day".” https://www.bbc.co.uk/news/health-39567240

## 3.2 Systems to monitor risks of mesh devices ignored by NICE

3.2.1 As far back as 2003 the Health Technology Assessment Vol.7 No.21 concluded that further research for the TVT implant should include:

a. Unbiased assessments of long-term performance (≥ 5 years) are required from follow-up of controlled trials and/or population- based registries.
b. There should be more data from methodologically sound RCTs to provide a more secure basis for assessing effectiveness and cost-effectiveness. Current trials (which are generally small) should be fully reported and include long-term follow-up. Further trials should be mounted where uncertainty persists, preferably independent of support from the manufacturers, and use standard outcome measures.
c. Ongoing surveillance of TVT would be enhanced by access to a regularly updated systematic summary of evidence from controlled trials, such as through the Cochrane Collaboration.
d. Research is needed on possible long-term complications of TVT; this would provide either reassurance of safety or earlier warning of unanticipated adverse effects.
e. If the indications for TVT are likely to be broadened to include women who are currently managed conservatively, this should be formally evaluated, ideally in an RCT, before widespread adoption.
f. As new evidence about the effectiveness, safety and costs of TVT emerges, this should be incorporated in updated cost-effectiveness analyses.
g. Evidence of efficacy (that TVT can be used successfully to treat incontinence) from case series led to the rapid, widespread adoption of TVT before its relative effectiveness (its place within NHS care) and long-term safety were known. Although current evidence suggests that TVT probably is effective and safe, this approach exposed thousands of women to an incompletely evaluated procedure in a poorly controlled way. Future research to evaluate new procedures of this type could avoid this by earlier and wider use of pragmatic RCTs and rigorously organised population-based registries.

https://slingthemesh.files.wordpress.com/2018/04/health-technology-assessment-of-tension-free-vaginal-tape.pdf

3.2.2 The NICE final appraisal 2003 chose not to include any of the HTA key recommendations, except for a recommendation as follows,

'*Further information on the long-term effectiveness and complication rate of the TVT procedure is required. It is recommended that observational data on effectiveness and safety of the procedure are collected over a period of 10 years or more. Preferably this should be nationally coordinated in the form of a registry of audit data to include both the numbers of procedures carried out and measures of outcome and adverse events.*'

3.2.3 The question for the Review is why, fifteen years later, this NICE recommendation has not been acted upon, especially given the persistent uncertainty over safety? Why did NICE ignore the list of HTA recommendations above? If all the HTA recommendations had been included and acted upon from 2003, then thousands of women would not be suffering life-changing injuries from mesh in the UK today. Furthermore, the findings arising from these recommendations would likely have been considered by governments and medical device regulatory authorities across the world, saving yet more women from life- changing injuries.

## 3.3 MHRA medical device adverse events monitoring ineffective

3.3.1 In a 2014 MHRA summary report of the evidence on the benefits and risks of vaginal mesh implants, MHRA states, 'Although we acknowledge there is under reporting of adverse incidents to MHRA, if there was an inherent safety problem with vaginal mesh, we would expect to see a far greater proportion of adverse incident reports from clinicians as well as from affected women.' Yet STM argues there is lack of awareness by patients of the Yellow Card reporting system and there are serious flaws in the this system and process resulting in vast underreporting of adverse events. Concerns were raised during the NHS England review of mesh implants that there was a lack of awareness for both patients and healthcare professionals about using the Yellow Card Scheme. STM members' knowledge and experience is as follows:

a. The MHRA, tasked with logging adverse events (AE) on its Yellow Card system, has failed miserably with just 1,279 incidents logged in a 12-year period. There are more than 7,000 members in Sling The Mesh support group alone. It should be noted that a surgeon can only log an AE from another surgeon's work if they get their permission thus adding a layer of bureaucracy to the system. This has kept reporting rates low.

b. The Yellow Card system is not user- friendly and needs to be reviewed with patient consultation.

c. The Yellow Card is a little known patient safety tool with few patients being aware of this system. STM members have commented they only heard of it by being alerted by the STM group. The founder of STM only heard about it through her cousin who is involved in campaigning for other issues.

d. A Google and social media trawl of Yellow Card takes you to information about football or an American Indie music band. There is virtually no information about

the patient safety reporting system. This is not good enough. No effort has been put into making patients aware of the ability to report problems with either medical devices or medicines.

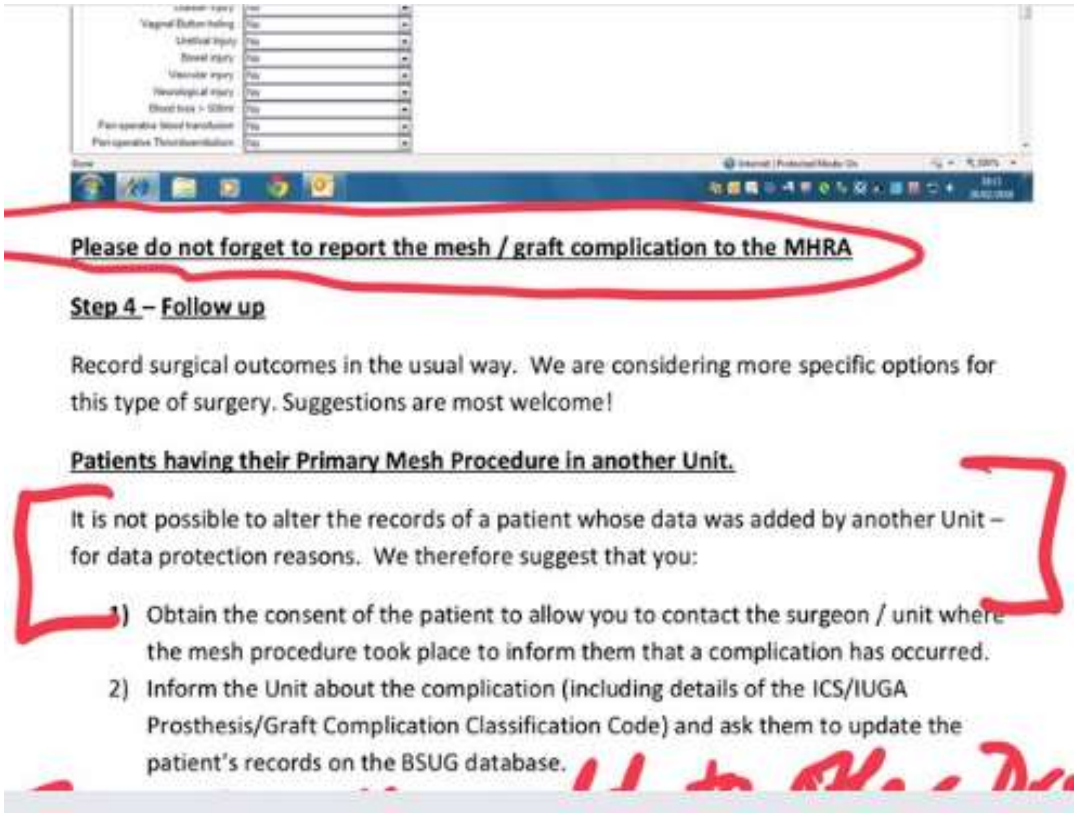
e. STM members have reported their confusion when completing the Yellow Card questions and inadvertently saying yes to manufacturers contacting them directly. Some women have been contacted by manufacturers after reporting to the MHRA such as Johnson & Johnson. But many resist replying to manufacturers as this presents a whole series of lack of trust questions, for example, their information being shared with a third party that they are not aware they consented to. This is particularly relevant given the new laws surrounding data and privacy. Those taking legal action against manufacturers/NHS/ clinicians are also unlikely to respond to contact from manufacturers.

f. Doctors/MDSOs often do not report the type of device or manufacturer of the product so products cannot be monitored. MHRA is bound by the Enterprise Act and cannot divulge commercial-in-confidence information such as trending data. Manufacturers investigate their own potential adverse events as MHRA does not have the facility. This is a conflict of interest. For example a lawyer in the USA has called for a criminal investigation into Johnson and Johnson after it was found thousands of documents were destroyed and hard drives wiped clean with information relating to pelvic mesh implants.

g. If a mesh affected woman wishes to lodge a device complaint she can do so with the MHRA Yellow Card. However, she needs to have the manufacturers name, make or serial number of her device to enable MHRA to log the complaint. Many women are not given all this information at the time of surgery. Often women have to seek assistance with this information from PALS and pay a fee for their medical notes, and sometimes the information is incomplete. If the mesh device was implanted more than 8 years ago some women have reported their notes have been destroyed as legally, hospitals are able to do so. A member of the STM Facebook group reported that her implanting surgeon was unable to confirm to her removal surgeon whether she had been implanted with a TVT or a TOT. Many more women report not being able to identify which mesh device was implanted. Therefore, it is essential that manufacturer/make and serial number of device is provided to all patients and their GP surgeries for logging on patients records at the time of surgery, as part of the informed consent process, in case patients need to report their device with MHRA in the future. This information needs to be included for clinicians in NHS guideline CG171.

3.3.2 In the MHRA surgeon guide for reporting complications, medics are not supposed to add a complication to another surgeon's work, hence impeding use of the Yellow Card system. How many surgeons will go to the trouble of getting a patient consent to contact their original surgeon, then wait for an answer and then log the adverse event into the MHRA? Most women need to see a different surgeon for mesh complications and removal, so the question remains why does the MHRA have this stipulation in its process of reporting? This flaw in the reporting system needs to be reviewed to address underreporting of adverse events.

## 3.4 MHRA systems led to underreporting of mesh complications



**Please do not forget to report the mesh / graft complication to the MHRA**

**Step 4 – Follow up**

Record surgical outcomes in the usual way. We are considering more specific options for this type of surgery. Suggestions are most welcome!

**Patients having their Primary Mesh Procedure in another Unit.**

It is not possible to alter the records of a patient whose data was added by another Unit – for data protection reasons. We therefore suggest that you:

1) Obtain the consent of the patient to allow you to contact the surgeon / unit where the mesh procedure took place to inform them that a complication has occurred.
2) Inform the Unit about the complication (including details of the ICS/IUGA Prosthesis/Graft Complication Classification Code) and ask them to update the patient's records on the BSUG database.

3.4.1 Jonathan Duckett's survey *'Mesh removal after vaginal surgery: what happens in the UK?*' published in the International Urogynecological Journal, 2016, indicated that there is considerable under-reporting of mesh complications to the MHRA. There is no denominator for this surgery, so it is impossible to estimate the incidence of complications of mesh surgery. Duckett states that only 27 per cent surgeons participating in the survey admit to reporting their mesh adverse events to the MHRA in this article:

https://link.springer.com/article/10.1007/s00192-016-3217-z

3.4.2 With regard to reporting mesh removals to the MHRA, the study reveals:

- 27 per cent of respondents reported all removals
- 38 per cent did not know of the need to report
- 16 per cent did not know how to report
- 11 per cent considered the reporting procedure too complicated
- 8 per cent considered reporting too time consuming
- of those who performed pelvic mesh insertion, 31 per cent reported removal due to mesh complications related to prolapse surgery

## 3.5 MHRA patient safety alert due to poor reporting

3.5.1 The MHRA issued a patient safety alert in 2014 to highlight the significant lack of audit for all medical devices. When reporting problems (not just mesh) 82 per cent of doctors did not record manufacturer name. A total of 65 per cent did not record product name, while 68

per cent did not record apparent causes of a patient problem. Around 40 per cent did not record outcomes because it was wrongly coded including death or serious harm.

https://slingthemesh.files.wordpress.com/2017/12/mhra-safe-from-harm-psa-med-dev-0414.pdf

MHRA has not provided a patient guide on risks for mesh procedures. STM believes a similar guide to that produced for valproate is needed.

www.gov.uk/guidance/valproate-use-by-women-and-girls


## 3.6 Ineffective structures in hospitals for MHRA reporting

3.6.1 From 2014 it became a requirement by MHRA & NHS England that there should be one Medical Device Safety Officer (MDSO) for every hospital due to

failures generally in doctors reporting issues i.e. to the MHRA. It has been reported that there is lack of clarity about these roles. In 2015 MHRA conducted an electronic survey to facilitate greater understanding of who MDSOs were, their sphere of influence in their organisations and experience in device safety as well as how much time they are able to dedicate to the role. MHRA did not reveal the answers to these questions in its follow up to the Stephenson Review, except that 57 per cent of respondents reported spending less than 5 hours per week on the role. What progress has MHRA and NHS England made in improving reporting through these posts and how effective have they been in addressing lack of reporting e.g. for pelvic mesh device adverse events?

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/441794/Report_on_progress_with_the_recommendations_of_the_Expert_Clinical_Advice__MHRA_Medical_Devices_independent_review.pdf

## 3.7 Lack of information on MHRA database for medical device adverse outcomes

3.7.1 There is no information on the MHRA website to search for adverse patient outcomes (unlike USA FDA database) so the public do not know which products have related issues and how many reports are made. Lord Porter of Spalding asked a question in the House of Lords in December 2017 on statistics from the MHRA on mesh insertion and mesh risk. The figures provided are known to be a fraction of the true figure due to vast underreporting.

https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Lords/2017-10-31/HL2734/

## 3.8 Omissions of outcomes in statistics

3.8.1 The York report, 2012, commissioned by the MHRA, did not include dyspareunia / loss of sex life in its final calculations of risk statistics. In a table of risks it shows dyspareunia at 14.5% yet this was not included in the final calculations as MHRA said this was not deemed to be a general risk. This omission keeps the figures low. It also devalues the right for a woman to have a healthy sex life. The York Report appears to cherry pick a few studies to conclude that risk is low. The report author's only qualification appears to be as a trained librarian. In addition, The York report was circulated for comment to MHRA external clinical contacts representing BAUS, BSUG and RCOG. Comment included: "We need to know the rate of complications of similar surgeries without mesh to compare these findings with".

http://www.cambstimes.co.uk/news/government-sling-mesh-tvt-vto-mesh-tape-incontinence-hospital-york-report-mhra-1-5259526

3.8.2 RCOG welcomed the York report stating it shows risk statistics are quite low using vaginal tapes for SUIs, generally in the range 1–3 per cent. Refer to York Report in this RCOG link:

https://www.rcog.org.uk/en/news/rcog-statement-on-report-commissioned-by-the-mhra-on-vaginal-tape-and-mesh-implants/

3.8.3 STM is concerned that MHRA may not be assessing all the codes necessary to calculate mesh related problems. Urethra/bladder repairs have not been mentioned as a code to be audited, yet it is one of the most costly repairs to carry out at £19,000. MHRA only appears to check codes for incontinence and removals. It is not known if MHRA has checked mesh exposure and suture repair codes.

3.8.4 To the layperson the data inputting on an MHRA excel spreadsheet of adverse events reports, including 13 mesh related deaths between 2005-2015, appears incomplete (see Annex 13). The differing data descriptions appear to make it difficult to compare adverse events leading to death and draw conclusions. The data presented appears to raise more questions than it answers. For example, why were manufacturers not contacted for all deaths, especially for all the cases where it is mentioned device design/excess device trauma? MHRA stated in their 2014 summary of the evidence on the benefits and risks of vaginal mesh implants, 'Although we fully recognise the limitations of interpreting data from these adverse incident reports to date, none of the final investigation reports has indicated that the devices have been inherently unsafe and required any enforcement action against the manufacturers by MHRA or removal from the market. However, many reports have been inconclusive, as there has not been enough information to be able to investigate the incident in-depth, although no fault has been attributed to the device.' In addition, the question remains did any of the death certificates for those patients recorded on the MHRA spreadsheet state mesh complications as a cause or underlying cause of death?

## 3.9 MHRA ineffective in its role

3.9.1 Former editor of the BMJ, Richard Smith, said in a recent article, "Regulatory approval of medical devices is generally much less onerous than approval of drugs. In the US devices judged as low risk can be approved on the grounds of being as safe and effective as existing devices, some of which may have been approved back before clinical evidence was required. In Europe some 50 "notified bodies" can approve devices on sometimes little more than a narrative review of published reports… Although the MHRA oversees the UK notifying bodies, the required evidence to let the device be marketed for clinical use is much less rigorous than in the drug industry. Randomised controlled trials are not required. The problem can be summarised by saying that manufacturers choose the methods of evaluation and the outcomes they will use, allowing lots of scope for potentially unsafe products to reach market." He goes on to say he is "worried that evaluation and regulation of medical devices is inadequate, convinced that there are better ways than are currently used to evaluate and regulate medical devices and that core outcome sets with the lead being taken by patients would be a step forward."

https://blogs.bmj.com/bmj/2018/09/25/richard-smith-improving-evaluation-regulation-medical-devices/?utm_campaign=shareaholic&utm_medium=twitter&utm_source=socialnetwork

3.9.2 STM has no confidence in the willingness or ability of MHRA to seriously address the mesh device scandal within its remit. This is evidenced in MHRA's recent response to a request by the CMO for feedback on the recently published NHS Digital report on pelvic mesh. It is imperative that an independent review of MHRA's response to the pelvic mesh device scandal is investigated and why they have been ineffective in their role. See STM's Action 5 for more detail on STM's concerns on governance issues in MHRA.

## 3.10 BSUG audit data concerns

3.10.1 One of the main concerns raised by campaigners and the Scottish and UK Parliaments has been the lack of available outcome data for individual surgeons performing pelvic mesh surgery.

**2013 BSUG audit data published four years after deadline**

3.10.2 According to BSUG, only a small percentage of surgeons doing this type of surgery enter their data on the BSUG database. As part of the response to these concerns, NHS England through HQIP (Healthcare Quality Improvement Partnership) decided that one of the mandatory national clinical audits for the 2014 Consultant Outcomes Publication (COP) would be stress incontinence surgery to show whether clinical outcomes for consultants are within expected limits. Yet despite a deadline to submit its 2013 audit data in August 2014, the results were not published until 2018, four years after the deadline. BSUG stated to STM that a change in leadership and funding issues to analyse the data were to blame for the delay.

3.10.3 STM waits with keen interest for the results expected in 2020 from the completed SIMS trial for which the BSUG database was used to record outcomes and follow up. The delay in presenting partial data is another example of how ineffective responsible institutions are in responding to the mesh scandal. BSUG is also known to have approached mesh device manufacturer Johnson and Johnson in 2010 to cover the costs of its new database highlighting potential conflict of interest.

https://slingthemesh.files.wordpress.com/2018/01/bsugcommitteemeetingminutesjan2010.pdf

3.10.4 The BSUG published the long awaited results of its 2013 audit in England on the day that the Review team suspended mesh (International Urogynecology Journal, 10 July 2018,). STM's belief is that the Audit's findings are of little value and add nothing new to the debate about the safety of mesh and actually support many of the arguments presented by STM

within this submission. According to the BSUG's 2013 audit, statistics show complication rates following the traditional alternatives are lower than mesh. STM's opinion is that this presents significant evidence to contribute to a permanent ban of mesh devices.

3.10.5 The 4,993 cases in the BSUG audit amount to only 42 per cent of the 11,913 procedures in NHS Digital data and removals were not mentioned. Furthermore, BSUG stated, "It is difficult to be precise, but this audit of gynaecologists collected almost 5000 cases from (probably) 8000 cases performed in that year by gynaecologists. The follow-up of 80% was good. "

3.10.6 STM has raised concerns about HES data within this submission. The BSUG also appears to share these concerns in stating the following**:**

"Other large data sets have been acquired using routinely collected data such as Hospital Episode Statistics (HES data) in England. According to the recent NHS digital retrospective review of mesh procedures, in 2013–2014, 11,786 synthetic tape surgeries were performed. This data is dependent on the accuracy of coding and does not provide any information regarding patient outcome and is of limited value in a clinical context."

3.10.7 The BSUG also made two further important points regarding the reliability of the data which supports the STM findings within this submission: -

- "Although use of the BSUG database was well established in many surgeons' clinical practice, not all surgeons performing continence surgery were entering their data on the database; many were not BSUG members, and some were urological surgeons."
- "There is a risk of reporting bias where users do not adequately record poor outcomes or complications. Some users may not report all cases or may have insufficient resources to chase full follow-up data. Variable follow-up points for outcomes may affect results."

3.10.8 Furthermore, by allowing surgeons in Wales, Scotland and Northern Ireland to voluntarily take part in the BSUG audit, STM believes this has further clouded the estimate of what was the overall figure of actual mesh surgeries performed in the geographical areas reporting on outcomes. This STM submission also highlights the many women who presented to GPs and/or Consultants and were told their problems were not mesh related. These will not be included in the 2013 audit. The BSUG audit also does not pick up the many women treated for their complications in A&E, by GPs and other consultants whose complications were never reported back to their implanting surgeon.

3.10.9 STM believes the BSUG audit is yet another example of short-term data analysis (up to only one year.) The majority of data is based on follow up visits at 6 weeks to 3 months,

in which the majority of mesh complications do not present themselves (dyspareunia, loss of sex life, erosion and chronic pain), given it can take years after implant before onset of these multiple complications. Hence SMT's call for life-long monitoring of patients for adverse events. Other notable findings from the audit, which support the STM position include: -

- "Long-term complications may be missed with this type of yearly audit."
- "Other countries in Europe have published audits," but BSUG stated, "The work we present here is different in that it describes the activity and risks of the different SUI procedures over the period of 1 year."
- "Severe complications were rare, but small numbers for operations other than synthetic tapes made comparisons difficult."
- "Table 2 shows using native tissue carries less risk than using mesh."

3.10.10 STM believes that only long-term data will reveal the true picture concerning adverse events and is therefore crucial, not simply 'useful.' STM are concerned that short term audits that declare mesh as safe and effective are misleading; especially this BSUG study that includes one author who is known to have been a paid consultant for medical device manufacturers.

3.10.11 BSUG failed to show in its 2013 audit results whether clinical outcomes for consultants are within expected limits. 'The initial aim of this audit was to provide yearly outcome data for individual surgeons and analyse outcomes of procedures for SUI, specifically, assessment of complications such as pain. Providing COP data, however, is a costly and labour-intensive process, and providing individual consultant outcomes would require a significant investment from government to provide this information on an annual basis.'

https://link.springer.com/article/10.1007/s00192-018-3705-4

3.10.12 Urologists at BAUS however, have published outcomes for individual surgeons, although the only outcome it appears to cover is whether urine leakage changed after the procedure. STM questions why BSUG cannot also publish their individual surgeons' outcomes?

https://www.baus.org.uk/patients/surgical_outcomes/sui/surgeons.aspx

3.10.13 The BSUG's reported 2013 audit findings also state,

"There is a risk of reporting bias where users do not adequately record poor outcomes or complications. Some users may not report all cases or may have insufficient resources to chase full follow-up data. Variable follow-up points for

outcomes may affect results." STM maintain that the same limitations apply to the BAUS data.

**BSUG audit data 2014-2018**

3.10.14 BSUG has also recently released its 2014 – 2018 database audit that shows 15 per cent complications from TVT, the most commonly used mesh sling in the UK. That is one in seven women suffering a peri operative or post operative complication. This is already a high figure but that is before problems of pain, voiding dysfunction, infection or loss of sex life are added. Unfortunately BSUG do not have this information to add as they do not ask questions for all these complications and focus instead on efficacy as the primary outcome.

3.10.15 This is evident as BSUG uses the Patient Global Impression of Improvement (PGI-I) which is a measure of how the patient feels after the operation and then ask patients the pad test question of how many pant liners / pads does a woman use after the operation. There is PGI-S for 'severity' of symptoms. Unfortunately, there is no PGI-S where S is for severity of complications.

**Problems with the BSUG database:**

3.10.16 By its own admission BSUG says: "Not every operation performed for the treatment of SUI over the last 10 years has been included in this analysis. In addition, caution must be applied to the use and interpretation of this report because of missing data and the limited recording of long-term outcomes – both positive and negative. This is particularly the case for long-term complications which may arise after the initial period of follow-up some of which will be treated in other units."

3.10.17 So it begs the question what is the point of this data when it is missing so much key information on mesh related complications and is so clearly flawed?

- Questions women are asked in this database focus on global impression of improvement after surgery with no chance to record new pain or problems. They are

  Very much better

  Much better

A little better

No change

A little worse

Much worse

Very much worse

- The database is self reported and voluntary. Fewer than 40 per cent of surgeons used this database. The fact it is voluntary opens the possibility of serious bias – the possibility of recording bad outcomes from non mesh and hiding them from mesh, unless the same surgeons use the database 100 per cent of the time for all their procedures.

- A table makes colposuspension and fascial sling look bad but both were used for many years – where was the mass litigation and where are the patients gravely injured by such procedures? There will be some, but if there were 1000s as with mesh, would a few not have come forward at least? This does not add up.

- There is no mechanism to record chronic pain, bowel problems etc.

- The numbers of colposuspension and autologous sling are very small

- Whilst they do clarify that "Much better" means much better for SUI at the start, for example in table 4 it does not make it clear it is for SUI. People with better SUI but bad pain would still be “much better”, which is misleading for the reader looking at the tables.

- Most follow up times (when recorded) were less than 6 months

- The 2.8% graft complication contrasts with HES code removal rates (6.5 per cent reported by Hannah Devlin, The Guardian. https://www.theguardian.com/society/2017/aug/15/scandal-of-vaginal-mesh-removal-rates-revealed-by-nhs-records)

https://bsug.org.uk/budcms/includes/kcfinder/upload/files/BSUG%20National%20Report%20-%20Stress%20%20Incontinence%20Surgery%20in%20the%20UK%20(2008-2017).pdf

3.10.18 STM is concerned that the BSUG database does not capture the issue of repeat mesh procedures. This study explains this issue in the UK whereby women are being given a second mesh when the first one fails. STM would like to see this issue properly highlighted in the BSUG database as currently it lists number of procedures but not the number of women to ascertain who was having a second or even third mesh.

3.10.19 The issue of repeat mesh procedures is discussed in a paper in 2017 in which Tincello et al states that 78 per cent of women are given another mesh on top if the first one fails.

Surgeons just leave the original mesh in. Not only is this bad practice but it will keep complication and removal rates low. Patient experience in STM shows that many women were either given or offered multiple meshes. This study makes it clear that surgeons do not have the skills to do anything other than mesh. So if this fails they have nothing else to offer. There is an urgent need for a retraining programme for existing surgeons and accredited training for new surgeons in the tried and tested traditional surgeries, for example Burch colposuspension.

https://link.springer.com/content/pdf/10.1007%2Fs00192-017-3376-6.pdf?fbclid=IwAR2CphSzi_os1NXEUUxqOMjZoJaOY5FKmx_Muv6SIky-RW1d0UT37k5y6qM

3.10.20 Most concerning in this study are five key discussion points:

1. "What was most striking was the dominant effect of repeat slings in every comparison in which it was included, a finding that was confirmed from the interviews as being a consequence of training and experience rather than an actual preference. It appeared that many respondents were unable to offer alternative procedures because they had not received training in procedures such as Burch colposuspension or autolgoous sling."

2. "This is an important finding not only for future research plans, but also as a training and clinical governance issue, bearing in mind the increasing concerns about Mid Urethral Tape complications, how they are managed, and the possibility of providing women with alternative choices."

3. "From the patients' perspective, the variability and inconsistency of surgeons' responses in general is a finding that will generate considerable concern, particularly given that this survey was only sent to those with specific training and a declared interest in pelvic floor dysfunction.

4. "Patients hope and expect that doctors know what they are talking about and that treatments offered are the most suitable/effective. However, it is clear from the data that the treatments women may be offered may depend largely upon the discipline and training of the surgeon, and that the choice of treatments offered depends upon the surgeon's skills, experience and opinion rather than any evidence.

5. "This highlights the importance of comprehensive and appropriate training, in addition to the need for research addressing the specific issue of failed continence surgery, to avoid and reduce the variability in patient choice that is currently present and to provide greater consistency of care provision."

## 3.11 BAUS incomplete outcomes data reporting

3.11.1 BAUS recognises in its latest SUI outcomes audit 2014-2017 that "shortfalls in data collection have been identified, and a longer follow up period is required to adequately comment on long term complications such as chronic pain and tape extrusion / erosion rates." BAUS states that 3 months post surgery 85 per cent of patients reported being satisfied or

very satisfied with the outcome of their procedure at follow up, although data entry for this domain was poor with only 63 per cent of patient follow up data recorded. The audit reveals the lack of complete short-term data available to BAUS and yet the conclusion is "excellent short term surgeon and patient reported outcomes and low numbers of low grade complications." The audit raises more questions than it answers.
https://www.ncbi.nlm.nih.gov/m/pubmed/30222915/

3.11.2 The data appears to show that the vast majority of urologists have not recorded any outcomes for SUI procedures, which could include mesh and non-mesh procedures. Since the type of procedure is not recorded, it would appear there is no way of BAUS knowing whether devices are being used and what type. Since there is no post surgery complication data recorded by urologists, there appears to be no way of knowing which type of procedure is causing which type of complication and to what extent. The data shows that there is no evidence being collected by BAUS on the safety of mesh from local UK clinical outcomes/audits and no evidence of safety of mesh devices in the UK from surgeons' reported outcomes. Given the ongoing concerns about the safety of mesh implants, it is of concern that BAUS has not undertaken a separate mesh audit as requested by NICE. Such an audit may shed light on the extent of mesh related peri-operative and post- operative procedures for specific types of complication long term. Only then could BAUS be effective in providing a much needed complication rate for mesh devices.

3.11.3 STM also believes the BAUS data adds nothing to the debate about whether SUI mesh is safe due to the following: -

- The study was only interested in changes in urinary leakage and pad use after surgery in its short follow up questionnaire.

https://www.baus.org.uk/patients/surgical_outcomes/sui/understanding_the_sui_graphs.aspx

- The reader could be confused that the data follows individual patients over a 3-year period, when it is actually only a one off post-operative spot check for complications for each patient at 3 months.
- Only 64 per cent of patients had follow-up recorded in the data. This means the complication rate in this group of patients could almost double.
- STM findings within this submission show that complications can occur within the first years but surgeons deny it is the mesh implant. Some women do not receive a mesh complication diagnosis until many years later, if at all. . The STM submission also highlights that many women presented to GPs and/or Consultants, were told their problems were not mesh related. Therefore, this data does not pick up the many women treated for their complications in A&E, by GPs and other consultants whose complications were never reported back to their implanting surgeon.
- This STM submission highlights limitations of data regarding mesh surgeries. There is no way of actually knowing the total number of mesh procedures in England or the rest of the UK for SUI, in order to establish a figure for complication rates.
- There is no explanation for the marked reduction in procedures from 2015, (this does coincide with the STM campaign becoming more visible in the media and litigation in USA).

3.11.4 BAUS has however, published its outcomes for individual surgeons. The data only includes complication rates and some patient reported outcomes (PROMS) for those units or consultants who have submitted follow up data on more than 50 per cent of their cases. This data therefore, is of little value for establishing the true complication rate and the nature of complications for mesh implanted for SUI.

https://www.baus.org.uk/patients/surgical_outcomes/sui/surgeons.aspx

3.11.5 BAUS also states, "higher risk patients are more likely to have complications. In addition, some procedures are inherently riskier than others. This also needs to be taken into account and is termed "risk adjustment".

https://www.baus.org.uk/patients/surgical_outcomes/how_we_do_risk_analysis.aspx

3.11.6 BAUS states, "There is considerable variation in data completeness and there is insufficient information for risk adjustment" and "the data presented are surgeon-reported, by entry into the BAUS Data and Audit System." There is, therefore, no method for reliably validating the data other than by comparing with the latest HES, which both BSUG and BAUS stated were unreliable**. "**There are no financial incentives (or sanctions) for hospitals and Trusts to support collection of SUI data, and this may also account for the data being incomplete." **STM questions** how then can the use of HES data be cited by BAUS as a reliable method to evaluate BAUS data?

3.11.7 STM believes the evidence in this submission shows that the true extent and seriousness of mesh complications are unknown. This means that '"risk adjustment,'" advised by BAUS, when considering patients for mesh surgery is severely compromised, even impossible. Furthermore, STM believes that the evidence in this submission shows that there is no 'safe' patient for mesh implantation regardless of "risk adjustment."

https://www.baus.org.uk/patients/surgical_outcomes/sui/about.aspx

3.11.8 STM questions whether it is safe to continue current mesh research (for example SIMS, VUE, PROSPECT) or start new trials, in view of the contents of this submission.

3.11.9 If mesh trials continue, STM recommends: -

1) An experienced and skilled mesh removal surgeon should be available as soon as complications occur, as mesh is designed to be a permanent implant.
2) All patients in current and future pelvic mesh trials should be made aware that mesh was suspended during the Review period; that complications should be reported to the MHRA as well as to trial administrators;

3) Ensure that all participants are given QOL questionnaires that are adequate to capture the onset of all mesh complications.
http://www.wisbechstandard.co.uk/news/mum-of-three-leaks-documents-to-sling-the-mesh-campaign-to-show-that-pain-suffered-after-her-operation-is-being-ignored-despite-being-part-of-a-trial-that-promised-to-monitor-her-for-three-years-1-4160667
4) Ensure a Clinical Audit is undertaken of all ongoing trials, to assess complications and whether the trials should be terminated.
5) In view of the current safety concerns, STM recommends the Review team write to the Ethics Committee for the SIMS, Vue and PROSPECT trials to ask why the trial results and interim 2-year results have not yet been published and to assess what complications are being captured.

### 3.12 Health Quality Improvement Partnerhip mesh audits

3.12.1 The HQIP website show just three reports about continence care, none of which include anything about pelvic mesh complications. More worryingly the last one was 6 years ago in 2012. STM wonders where the updated HQIP data is. STM is invited to a HQIP meeting in November 2018 but is this really the case that there is no HQIP data from 2012 to 2018? STM is not aware if the full mesh HQIP audits with national results undertaken by NHS Trusts implanting mesh have been published. This document should summarise how many NHS Trusts failed to comply with the audit. STM believes this information may support the position that there is inadequate local UK data from local clinical outcomes over the last 15-20 years. All HQIP audits should have a national public summary of audit in the public domain. The 2010 report quoted *NICE guideline CG 40: 5.2: "Procedures for stress urinary incontinence…"Synthetic slings using a retropubic 'top-down' or a transobturator foramen approach are recommended as alternative treatment options for stress UI if conservative management has failed, provided women are made aware of the lack of long-term outcome data."* STM's experience is that this guideline has not been followed.

https://www.hqip.org.uk/resource/national-audit-of-continence-care-reports-from-2010-2012/

## Action 4. An overhaul of the HES reporting system to ensure ALL mesh complications are recorded for a patient's lifetime and to retrospectively correct the vast underreporting of mesh complications to date through a national recall

### 4.1 Absence of data

4.1.1 A fundamental and hazardous absence of data is at the heart of the pelvic mesh scandal in both the NHS and private sector. There has been careless practice, and this must not be allowed to continue. STM are pleased to hear Jeremy Hunt's statement that 'We are particularly considering the issue of data sharing, because often clinicians operate in both the NHS and the private sector, and we want to make sure that we do not have two datasets but that we share data in a way that makes patients safer.'

4.1.2 It was acknowledged by the NHS Mesh Working Group that there were issues surrounding the HES data collection and reporting of adverse events in relation to the use of

mesh. They recommended that improvements were needed for hospital episode codes; Yellow Card Scheme; improving clinical leadership to promote awareness of the importance of adverse events; the setting up of a registry of pelvic mesh implants; the development of a registry to track mesh devices and complications. BAUS supported these recommendations, but funding needs to be available to enable improved capture of data:

https://www.baus.org.uk/_userfiles/pages/files/professionals/sections/female/Response%20to%20NHS%20England%20mesh%20recommendations.pdf

4.1.3 NICE guidelines for medical professionals on pelvic mesh states 'Following the publication of the interim report the Mesh Oversight Group was formed to oversee the implementation of the recommendations made. These recommendations have been successfully implemented of which one was the creation of this resource.' This statement is ambiguous as there are a number of actions that have yet to be implemented including revision of HES coding (see paragraphs 4.4 - 4.5 below).

4.1.4 The Review needs to investigate progress with all of the NHS Mesh Working Group recommendations and timeframes to address the vast underreporting and gaping holes in data collection. STM advocates for a national recall to include women who have had a pelvic mesh device implanted over the past 21 years. A public helpline, should also be set up, staffed by appropriately knowledgeable call handlers. This should include all types of pelvic mesh especially given HES reporting codes are lacking or do not exist for this particular surgery. This is the most effective method to obtain real data on adverse events if the government are truly committed to obtaining the true scale of the problem. Patient groups such as STM should be consulted regarding the type of complications to be considered in a national recall to ensure that none are omitted as has previously occurred. Many of the validated questionnaires currently in use in research are not adequate to capture all complications.

4.1.5 In relation to fundamental gaps in HES coding the NHS Mesh Working Group stated in its July 2017 report that,

> 'there are no specific HES OPCS-4.7 codes to classify full or partial removal of vaginal mesh for POP. Therefore the group recommends that new OPCS codes should be developed to reflect complications, which result in full or partial mesh removal and the reason for this. A small working group should be established to look at this issue for both POP and SUI and advise on what requests need to be made to HSCIC to introduce new codes in future versions of the OPCS to address this. There are also no specific codes for salvage surgery for POP and SUI. There are no specific codes that specifically classify the above terms. It is clear that there is a gap in OPCS coding which needs to be addressed. Collection of these data will allow for more accurate complication rates to be calculated across POP and SUI procedures.'

There is no information as to the progress being made by the Mesh Working Group in recommending changes to the system and process of HES coding.

## 4.2 NHS Digital audit report errors

4.2.1 STM does not believe the NHS Digital Audit report data on pelvic mesh published in April 2018 stands up to scrutiny. It even calls it 'experimental data'. STM has the following concerns:

- The report is incredibly difficult for the layperson to understand, and STM wonders therefore, for which audience the report was produced.
- The report did not include a Terms of Reference.
- It is not apparent that there was any patient input for the dissemination.
- The removal rates shown in the audit are about half compared to rates provided by NHS Digital in the summer of 2017 to the Guardian publication that published the data. Nobody complained to the Guardian or asked for a retraction of this figure then.
- This audit covers England only, there is no data included from N. Ireland, Scotland and Wales.
- This audit was termed as 'experimental' data. In terms of data analysis, STM is not aware of the term experimental (based on untested ideas or techniques). We take it to mean the data is not validated. It is not robust. This is too important a task to use 'experimental' data when the frequency of extremely serious complications are being measured.
- Concerns have been raised by STM but a satisfactory reply has not yet been received.
- See Annex 5 for full list of missing data

4.2.2 MHRA's recent response to a request by the CMO for feedback on the NHS Digital report on vaginal mesh is an example of MHRA's failure to seriously address the pelvic mesh scandal within its remit. Compared to the responses of BAUS, BSUG and RCOG, all of which had analysed the data and identified gaps, MHRA in comparison did not refer to the detail of the report in its response. See Annex 5 for responses by above institutions.

# Action 5. Review the governance, accountability and effectiveness of the medical profession

## 5.1 Independent review of MHRA's response to the pelvic mesh scandal

5.1.1 STM questions the lack of governance and accountability of the medical profession, including all relevant institutions responsible for patient safety, regulation, monitoring and evaluation of the safety of mesh implants in the NHS and private sector. This is particularly relevant given the history of poor reporting, misinformation and flawed research to date.

5.1.2 STM queries why an independent review of MHRA's response to the pelvic mesh device scandal has not been initiated and whether MHRA has been effective in its role. STM strongly believes there is an urgent need for a review of MHRA's governance relating to the mesh medical device regulation process, especially in view of Brexit. MHRA needs to look to the past to protect the future. Medical devices should be treated as 'guilty until proven innocent', given the pelvic mesh scandal.

## 5.2 Governance issues of MHRA

5.2.1 It has long been reported that the MHRA has been too close to the industry, a closeness underpinned by common policy objectives, agreed processes, frequent contact, consultation and interchange of staff. STM members have little faith in the ability of medical institutions that are responsible for patient safety to be open and transparent over patient safety failings. The following illustrates how MHRA is keen to divert the bright lights of close scrutiny away from its own performance and role in the system.

https://www.theguardian.com/society/2017/apr/21/nhs-vaginal-mesh-implants-scandal-suppress-media

http://www.cambstimes.co.uk/news/leaked-documents-show-a-powerful-patient-safety-group-wants-to-keep-the-mesh-implant-scandal-hidden-1-4978781

## 5.3 Accountability concerns in MHRA resourcing

5.3.1 Stephenson's 2014 report of the independent review on MHRA access to clinical advice included a key recommendation to ensure that adequate clinically trained staff are included in the MHRA staff. He stated:

'*It is essential that the Agency has clinical leadership within its Devices Division that is capable of peer-to- peer dialogue with leaders of the professions and has the capability to provide strong strategic leadership both within the Agency, across government and in the broader healthcare community in the United Kingdom, Europe, and beyond.*'

5.3.2 While a new Clinical Director of Medical Devices was subsequently appointed in 2014, it is understood the current Head of Device Regulation has a degree in zoology. He is not a medical professional or scientist, but has a previous career advocating for the interests of the medical device industry. He has been a keen promoter of medical devices and minimally invasive surgery as outlined in many of his articles while previously employed by EUCOMED (see articles below.) In STM's view this raises a question of conflict of interest given his role is to report problems involving medical devices. This clearly suggests to STM that MHRA may have failed in its role in reporting problems of pelvic mesh over the past 20 years.

*http://www.medtechviews.eu/article/procurement-–-kill-or-cure*
http://www.medtechviews.eu/article/want-reduce-healthcare-spending-it's-all-about-looking-right-places

5.3.3 STM believes the MHRA's Yellow Card system should be replaced with a more transparent 'Maude' type database system (for example as used in the USA), so that reports regarding complications and adverse events on medical devices are open to public scrutiny

## 5.4 MHRA attempts to hide the mesh scandal

5.4.1 The MHRA Devices Division investigates reports of problems involving medical devices. The results of these investigations are used to advise healthcare professionals on the safe use of devices. In a leaked email from MHRA, staff were tasked with '*taking the press element out of the mesh yellow card campaign. Investigate whether there can be a general yellow card campaign, of which mesh is one element, to avoid attention on mesh*' (see below.)

Please see link:

https://www.wisbechstandard.co.uk/news/leaked-documents-show-a-powerful-patient-safety-group-wants-to-keep-the-mesh-implant-scandal-hidden-1-4978781

## 5.5 Failings in BSUG and RCOG

5.5.1 STM believes BSUG is not fit for purpose. The BSUG database was set up as a limited company in 2009 with various surgeons as directors. It was dissolved in October 2014 as a PLC, just two months after the BSUG deadline ended to submit data for its 2014 audit. It has only just published its 2013 statistics for HQIP as highlighted in detail in paragraph 3.10.1 above. There appears to be no information publically available as to why BSUG was established as a PLC and why no results have been forthcoming when requested;why BSUG was dissolved, who now owns it and who holds the data. It is unclear whether BSUG now has charitable status, who supports it and who donates.

5.5.2 Section 3.10 of this submission provides detail of BSUG's failure to report audit data. It is also worth highlighting here that in August 2010 the ICS UGA highlighted BSUG's failure to record the majority of vaginal prolapse surgery with synthetic mesh and a high level of missing follow up complications data. Long-term follow up data was not recorded at all, which may reflect the reliability of self-reporting.

https://slingthemesh.files.wordpress.com/2018/01/ics-call-out-bsug-for-not-reporting-to-their-database.pdf

5.5.3 STM queries why BSUG and RCOG have been taking the lead in pelvic mesh discussions. STM is appalled at the history of denial and is concerned at the apparent approach over many years of 'burying their head in the sand' to pelvic mesh concerns**;** particularly the lack of action in instigating clear and timely pathways of care for mesh injured women suffering pain over the past 20 years. STM questions why the British Society of Gynaecological Imaging and the British Pain Society have not been consulted in any of the pelvic mesh discussions.

5.5.4 RCOG's strategic plan for 2017–20 aims to fulfil twin ambitions of becoming the 'go-to' place for women's health in the UK and a global leader for women's health and reproductive health care:

- Ensure gynaecology services receive equal attention, noting that gynaecology often has a lower priority than maternity care, despite the significant gynaecological demand on A&E services.
- Patient safety across RCOG should be a priority at all times, achieved by incorporating the patient experience, including patient reported outcome measures (PROMS) and interactive patient information, and developing the invited review service.

5.5.5 RCOG's website information page on mesh states,

'For many women, surgical procedures using mesh provide an effective form of treatment for the distressing effects of SUI and POP. However, some women experience serious complications and there are a number of patient communities who campaign to raise awareness of these concerns.'

5.5.6 STM queries what evidence has RCOG based its conclusion that only 'some' women experience complications, when a recent study shows that less than 40 per cent of surgeons have reported to the BSUG database and less than 27 per cent reported all mesh removals to the MHRA (Duckett et al, 2017). How does RCOG know that 'for many women' mesh devices are effective given there is vast underreporting of complications? STM's view is that RCOG has not been listening to patient voice, particularly relating to pelvic mesh complications. STM questions why RCOG has not advocated for a suspension of pelvic mesh given thousands of

women have been injured in the UK. This is of concern given RCOG's ambitions are to be the 'go to' place and global leader for women's health care.

5.5.7 STM's view is further supported by the follow up questionnaire issued by the BSUG Audit and Database Committee, to women after mesh proplapse surgery. Follow up only continues for one year, which in itself is inadequate as onset of mesh complications can occur years after surgery. The questionnaire is too brief, contains no guidance on how to interpret the questions, and is only interested in the post-operative condition of the patients' prolapse. Therefore, complications such as pain, perforated bowel, dyspareunia, mobility and many other complications remain unreported. Furthermore, clinicians often dismiss the fact that many women's complications are related to mesh. Therefore, women would not know to mention them during any follow up after surgery, because they have been told they are not mesh related.

https://bsug.org.uk/budcms/includes/kcfinder/upload/files/BSUG%20PGI-I%20Prolapse.pdf

5.5.8 The BMJ has also highlighted the limitations of using questionnaires, 'Randomised trials are subject to strict reporting criteria, but there is no comparable framework for questionnaire research. Hence, despite a wealth of detailed guidance in the specialist literature, elementary methodological errors are common. Inappropriate instruments and lack of rigour inevitably lead to poor quality data, misleading conclusions, and woolly recommendations.' https://www.bmj.com/content/328/7451/1312

5.5.9 STM wonders whether clinicians have been reluctant to stop using pelvic mesh owing to a 20 minute procedure to implant SUI mesh that will earn them a fee in private practice of £589 for TVT; while a traditional Burch Colposuspension procedure takes 3-4 hours of surgery time and two patient follow up appointments. The fee for a colposuspension procedure is less than for a mesh implant at £548 (source: BUPA fee checker see link below)

https://codes.bupa.co.uk/procedures

## 5.6 Lack of standard requirements for training and competence for mesh insertion and removal surgery

5.6.1 Currently mesh surgeons may be members of various different professional organisations (e.g. BSUG, BAUS, BCOG), which operate different voluntary reporting systems. There are no standard requirements across professional organisations as to what constitutes an accepted level of training and competence to perform mesh surgery. This is evidenced by the letter and instructions to hospitals circulated by NHS England on 20th July 2018. The lack of accredited training for mesh insertion and surgeon's learning curve has led to mesh being placed in the wrong position causing immediate complications for women.This has led to partial removals or trimming/snipping of mesh,, which have made complications worse, because the mesh frays and migrates.

5.6.2 In 2014 AJOG published a multi centre analysis of mesh complications in women who had mesh inserted between 2006-10 in which it found, "physicians who perform these mesh procedures may not be aware of the complications their patients experience and that these providers may be responsible for future mesh

related complications with no awareness of the existing magnitude of the issue." The situation in the UK is similar, in that women are often treated for complications by surgeons who did not implant the mesh. This impacts further on the under reporting of complications.

5.6.3 The AJOG article also stated that when complications do occur, they are "usually severe and require surgical intervention." Furthermore, "there was no guarantee of symptom resolution." The study does not indicate the length of time after implantation that complications were occurring within the 4-year analysis period. The study was unable to identify the rate at which complications occur, due to lack of data.

https://www.ajog.org/article/S0002-9378(13)01065-X/fulltext

5.6.4 STM has strong concerns over repeat mesh procedures. A survey in 2017 by Tincello et al rings alarm bells for STM. The study reveals the extent of preference among surgeons for mesh compared with traditional repairs for repeat surgeries when the first surgery has failed. There was a clear preference for leaving the original mesh device in position when dealing with failure of the existing midurethral mesh tape by 78 per cent of surgeon respondents. The study findings also show that urogynaecologists were more likely to offer a repeat midurethral tape compared to urologists. Most concerning in this study are five key discussion points in the study as follows:

i. "What was most striking was the dominant effect of repeat slings in every comparison in which it was included, a finding that was confirmed from the interviews as being a consequence of training and experience rather than an actual preference. It appeared that many respondents were unable to offer alternative procedures because they had not received training in procedures such as Burch colposuspension or autologous sling."

ii. "This is an important finding not only for future research plans, but also as a training and clinical governance issue, bearing in mind the increasing concerns about Mid Urethral Tape complications, how they are managed, and the possibility of providing women with alternative choices."

iii. "From the patients' perspective, the variability and inconsistency of surgeons' responses in general is a finding that will generate considerable concern, particularly given that this survey was only sent to those with specific training and a declared interest in pelvic floor dysfunction.

iv. "Patients hope and expect that doctors know what they are talking about and that treatments offered are the most suitable/effective. However, it is clear from the data that the treatments women may be offered may depend largely upon the discipline and training of the surgeon, and that the choice of treatments offered depends upon the surgeon's skills, experience and opinion rather than any evidence.

v. "This highlights the importance of comprehensive and appropriate training, in addition to the need for research addressing the specific issue of failed continence surgery, to avoid and reduce the variability in patient choice that is currently present and to provide greater consistency of care provision."

The following statements were made by surgeons participating in the survey on their preference for repeat mesh use:

*"[I do it] because it's easy. I mean I've done a couple, just sort of snipped out the middle bit of the tape that was there...and put another one in, and so far they've done, they've done well*." (Participant surgeon S01)

"*My suspicion is that, you know, some people, rather than referring them to somebody else who might be able to offer these other options, they just get a repeat tape... and of course a tape is a good operation, you know, it's got a good benefit risk profile, you know, it's not very interventional, and it's got, and it's got good successes*."(Participant S12)

The declining expertise in the more invasive procedures was commonly discussed as an important factor underlying the preference for repeat mesh tape procedures:

"*There's only [a] percentage of people who can do a sling (autologous), and it's quite a small one. And in fact increasingly there will only be a small group that can do Burches [colposuspensions], you know fluently and comfortably, so I mean one of the problems is there are lots of surgeons who have very limited repertoires and so that limits them to what they can do*. "(Participant S06)

5.6.5 This survey raises a number of concerns for STM as follows:

i.The incidence of repeat mesh procedures and outcomes are not being reflected in any of the current data. Mesh removal rates are not an indication of the true mesh complication rates. According to table 2/figure 2 in section 2.3 in the BSUG audit data just 5.9 per cent of retropubic TVT procedures were repeat procedures. The BSUG data appears to contrast with the Tincello study.

https://bsug.org.uk/budcms/includes/kcfinder/upload/files/BSUG%20National%20Report%20-%20Stress%20%20Incontinence%20Surgery%20in%20the%20UK%20(2008-2017).pdf

ii. Surgeons are biased towards mesh use as they are unable to offer alternative procedures because they have not received training in standard procedures such as Burch colposuspension or autologous sling. This issue links to the failure of the ethical principle of informed consent.

Tincello study: https://link.springer.com/content/pdf/10.1007%2Fs00192-017-3376-6.pdf

## 5. 7 Industry funding of consultants and medical institutions

5.7.1 The whole mesh tragedy began with a shocking conflict of interest. Jonathon Gornall reported in a recent BMJ article that in 1997 a small study of 75 women were treated in Ulf Ulmsten's department at Uppsala University Hospital, Sweden, with what became known as the tension-free vaginal tape (TVT) procedure that gave impressive results. Ulmsten then organised a larger, multicentre study to find out how easy, effective, and safe the procedure could be. Even before this second study got under way Ulmsten's company Medscand had signed a licensing agreement in 1997 with Ethicon, a subsidiary of Johnson and Johnson. The latter agreed to pay Medscand a series of payments that amounted to $1m provided that the proposed second trial upheld the findings of the first. https://www.bmj.com/content/363/bmj.k4155

5.7.2 It has long been reported that a number of consultants have accepted benefits sponsored by mesh medical device companies to encourage the widespread use of pelvic mesh implants. This includes funding for training, travelling fellowships, honoraria, consultancy fees and meals. It is also known that numerous studies sponsored by mesh manufacturers have revealed the anatomical benefits of pelvic mesh devices, while ignoring the safety risks, culminating in bias and conflict of interest.

5.7.3 A US Lawyer, who gave evidence to the Holyrood committee, urged the MHRA to "look at the studies that are relied on by the mesh manufacturers. Most of the studies they rely on are written or investigated by paid consultants," he said. "I would throw those in the garbage immediately because if somebody is being paid by the manufacturer, there is a financial bias." He added: "There has never been a high-level study...that has ever been done that has proven the mesh to be safe and effective."

https://www.dailyrecord.co.uk/news/scottish-news/mesh-surgery-scandal-lawyer-likens-5222867#ICID=sharebar_twitter

5.7.4 It is apparent that some consultants continue to refer to the flawed Nilsson study as proof of the efficacy of mesh use. For example Cardozo's recently published 'Article of the Week,' BUJI, 11 July 2018 (published the day after the Review team suspended the use of mesh.) This article (see link below) was criticised by STM members and other senior clinicians for being unbalanced and biased. It is known that Cardozo has been a paid consultant for Ethicon, a TVT mesh manufacturer. This may explain her position in declaring TVT as a safe and effective option in this article.

http://www.bjuinternational.com/article-of-the-week/editorial-can-still-recommend-tension%E2%80%90free-vaginal-tape-long%E2%80%90term-safety-efficacy/

5.7.5 In 2005, however, in the BJOG Cardoza and Bidmead expressed views similar to those of STM. “Estimating the true incidence of problems related to synthetic slings is complicated by the fact that many problems related to erosion may not become apparent until relatively late, one to four years post-operatively” and, “Problems related to erosion of the sling material, through the vagina or urethra, appear to be encountered almost exclusively with synthetic sling materials… graft erosion can pose a formidable management problem with persistent vaginal discharge, vesicovaginal fistula formation and fibrosis, and destruction of the urethral sphincter. Assessing the true incidence of such problems is difficult, as many early reports of new sling techniques did not feature sling erosion even when using materials now well known to cause problems.**”**

5.7.6 Cardoza concluded (in 2005), “Sling procedures are currently enjoying a revival of interest. If we are to advance our understanding of these techniques, randomised trials with thorough evaluation of surgical procedure, objective and subjective outcomes, and complications over at least a five-year follow up, will be required.” STM are appalled that long-term trials, with an appropriate population sample, have still not been undertaken. The BMJ reported that, “ In June 2014 Cardozo was a cosignatory of a letter sent to members of RCOG after the “unexpected” decision by the Scottish government to suspend the use of all mesh for treatment of stress incontinence and pelvic organ prolapse, which, said the letter, would “cause alarm to women not only in Scotland but in the rest of the UK.” The BMJ reports that Cardozo has received funding from six drug manufactuers.

https://www.bmj.com/content/363/bmj.k4164

https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/j.1471-0528.2000.tb11683.x

5.7.7 Robert Bendavid MD, University of Toronto & Shouldice Hospital, wrote a letter to the Review team in July 2018, (shared with STM), in which he states,

“What seems like an insurmountable problem has been the cronyism and the conflicts of interest which is rampant among surgeons. I had an important role in the creation of the American Hernia Society in 1997 and looking back, this was our biggest mistake. As a past president, one sees the errors we have committed. Allowing the industry on the board of societies has to be the most egregious step that was ever taken. Companies now can address the leadership without bothering with the rank and file which does the majority of surgery… I wish your committee abundant illumination in this dreadful situation where such companies are presently being investigated for the illegal importation of substandard polypropylene, illegally from China at a time when US companies refuse to make it because the polypropylene was not intended by Phillips Petroleum to be used in humans.”

5.7.8 Industry funding of professional bodies is also common. For example, the BMJ reports that "RCOG offers Ethicon awards to its members. In 2016 three members received "student elective awards" and one senior consultant was given a travel award. Accounts for the year to December 2015 (the most recent that are publicly available) show a contribution of £133,402 from Ethicon." The UK Pelvic Floor Society, whose members use synthetic meshes for prolapse and incontinence surgery, is supported by Shire, Cook Medical, Medtronic, THD, and BK Medical. https://www.bmj.com/content/363/bmj.k4164

5.7.9 The lack of transparency in funding by industry of the medical profession leads STM to believe that there is bias towards pelvic mesh devices and that conflict of interest has likely played a significant part in the widespread adoption of mesh for the treatment of pelvic organ prolapse and stress urinary incontinence. Robust mechanisms need to be put in place to ensure transparency and scrutiny around declarations that are currently not open to public scrutiny. STM believes similar legislation to the USA Sunshine Act is required. See Action 10 for more details.

## 5.8 Lack of informed consent

5.8.1 Lack of informed consent is a substantial aspect of the pelvic mesh scandal in which 90 per cent of women respondents in a Sling The Mesh survey, 2017, stated they were not given informed consent before surgery despite the Montgomery Ruling. Women of child-bearing age were also not told of risks of mesh and some subsequently encountered severe complications with subsequent pregnancies and birth. Even today some surgeons during consultation say they do not use the mesh mentioned in the media or they call the SUI mesh a tape, ribbon, gauze, band or sling. One surgeon likened the sling to 'a teddy bear hugging the bladder.' See Box 6 for further comments. The downplaying of risks by certain clinicians and lack of standardised consent forms and process stating all the mesh risks, have contributed to lack of informed consent. STM also questions whether truly informed consent is even possible when true long term complication rates are unknown.

5.8.2 Junior health minister Jackie Doyle-Price has said the vaginal mesh scandal, in which thousands of women had to have implants removed because of complications, was "an example of how there isn't a proper conversation between women and health professionals about the conditions that affect them". Women, in particular, needed "much more informed consent" to any procedure or medication they were given, she said. Yet, Doyle-Price has previously stated that the mesh device itself is not the issue but clinical practice. How can informed consent be given if the truth about the device itself as well as clinical practice are not addressed?

https://www.theguardian.com/society/2018/jun/29/women-often-feel-patronised-by-doctors-health-minister-says
https://oag.ca.gov/system/files/attachments/press_releases/J%26J%20Complaint_1.pdf

https://www.drugwatch.com/news/2016/08/17/civil-mesh-suit-filed-against-jj/

5.8.3 MHRA stated in its 2014 summary report on the benefits and risks of vaginal mesh implants, 'Some of the information provided to us has indicated other areas of concern associated with the use of vaginal mesh implant surgery that are outside of MHRA's remit, such as lack of comprehensive informed patient consent and lack of awareness of possible complications that are expected to occur from vaginal mesh implant surgery. There have also been indications that there may be a lack of knowledge amongst some GPs and clinicians about what types of adverse events may occur.' The EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) issued their 'Opinion on the safety of surgical meshes used in urogynecological surgery' in December 2015 that states,

'*Many patients are still undergoing mesh surgery as a first option without having all the necessary information regarding the potential risks. Unless worldwide standardisation of guidelines and statistically accurate information identifying the potential risk in the use of these products is adopted, then true informed consent cannot and is not being obtained from the patient. Information given to practitioners by the manufacturers regarding the 'proven' safety of these products and the 510k clearance loophole needs to be addressed before true informed consent can be made*.'

**Box 6: STM mesh-injured women's comments on lack of informed consent by doctors**

"Asked if I'd seen papers recently I said no, he said good as all media hype anyway."

"I was told of risks during operation but not long term risks."

"I believe that he said that I might need it redoing after 10 years."

"Just before I went down to surgery, no time to digest it and investigate it."

"I was given a leaflet but erosion wasn't explained and it was said complications are extremely rare so I don't need to worry about that!"

"He gave a pamphlet with possible side effects but said not to worry it's not the bad mesh just tape. We perform these simple ops every day and nothing to worry about. These forms are just a precautionary due to today's culture . You will be fine."

"Just less than 1% chance it will not work."

"TVT is not mesh."

"It is different mesh to what's in the news'."

"My surgeon warned me all about how the previous mesh was not good and there had been women who had suffered complications from this. He then showed me 'tape' which apparently wasn't the previous mesh, but now of course I know that it was"

"Don't read the horror stories about mesh, the one that people are having problems with is not the one we are using now,"

"Yes but not sufficiently explained or how long these would last or the severity"

"I was the one who brought up concerns and she said they were all not applicable to me because 1) She was the best surgeon in the UK, lectured around the world on vaginal mesh, repairs everyone else's mistakes and if she did it there would be no problems; and 2) I had no risk factors and all problems with mesh are either surgeon error or the fact that a patient has other issues such as being overweight, which I wasn't (my BMI was only 18.5 as I was training for a half marathon and was a runner), I wasn't in menopause and she said any problems could be easily fixed. I have that bit in writing. She said there was only a slight risk of erosion, which is all she told me. She said erosion was easily fixed. She explained it as a little piece of tape so she downplayed every single risk there was. I'm so frustrated with myself that I let her talk me into this surgery. She also told me that the mesh was the best surgery even though she told me about the other two. She really only told me about the other two flippantly...as if they were stupid choices."

*Source: STM members Facebook forum 2017- 2018*

5.8.4 STM is concerned that consultants may be informing patients they are an 'appropriate patient for selection' for a mesh implant to treat SUI or POP, when in fact first-line conservative treatment options have not been offered. SMT does not believe there is an 'appropriate patient' for pelvic mesh devices, given the evidence that, for example, polypropylene eventually changes architecture in the body and degrades, causing complications years after implant.

5.8.5 Many STM members suffering from mesh complications have been told by their surgeons that it is too difficult or too risky to fully remove mesh. Surgeons will often only recommend partial mesh removals (that are now understood by STM to be ineffective and can cause more damage as the mesh may further fragment and migrate in the body). The question remains for STM members, why are surgeons implanting a risky device that surgeons often say later are too risky to be fully removed? Many STM members are angered that they were not fully informed that devices were intended to be permanent and feel they have been treated as 'guinea pigs.' See Cundiff and Slack_et_al-2018-BJOG_Managing mesh complications.

5.8.6 NICE recommends that 'it is highly advisable women consider a mesh implant procedure only after their family is complete. While it will not affect women's ability to become pregnant, there is an anticipated increased risk of failure of the tape procedure following pregnancy and childbirth. A Caesarean section may be recommended to reduce such risk.' A number of STM members with mesh implants have suffered increasing pain in pregnancy and traumatic births and miscarriages. They report also having received conflicting advice about caesarean vs. natural birth. Some were advised by their surgeons that mesh should not be implanted if they intended to have children afterwards, but some were not.

5.8.7 On 12th July 2018 (two days after the Review team suspended the use of mesh) a UK firm providing professional legal insurance for surgeons, issued a "Use of Mesh - Important Update" stating, "In the event of a complaint or claim regarding the management of patients with SUI or POP, you can request assistance from Medical Protection in the following circumstances:

- The patient's care was delivered by an appropriately trained specialist gynaecologist, urologist or colorectal surgeon holding a substantive post at a specialist unit who maintains a multidisciplinary team approach, including in private practice, having fully explored all available non-operative and surgical options for the patient's condition.
- The specialist member belonged at the time of their professional involvement to one of the following specialist societies: British Association of Urological Surgeons (BAUS), British Society of Urogynaecology (BSUG) or Association of Coloproctology of Great Britain & Ireland (ACGBI). The relevant professional guidance regarding patient selection and mesh use must have been followed.
- The specialist participated fully with reporting requirements (for example, MHRA, hospital clinical governance reporting systems, BSUG or BAUS databases, if relevant) and appraisal in relation to mesh use and management of mesh complications.
- There is evidence of informed patient consent, which includes explaining the potential risks and benefits of all available treatment options."

5.8.8 STM believes this may be a case of shutting the stable door after the horse has bolted and appears to be an admission that appropriate professional practice has not been followed. The Hilton study published in the IUJ April 2016 highlights weaknesses in surgeon training. It states, "Mid-urethral tape procedures brought a paradigm shift in surgery for stress incontinence; little research into the development and maintenance of surgical competence for the procedure exists." The hypothesis for the study conducted was that the 'learning curve' for retropubic mid-urethral sling procedures, judged by the surrogate of bladder perforation, is longer than previously thought." The study's conclusion was that "while seductively simple in concept, mid-urethral tape procedures are not without risk; their inherently 'blind' nature makes them difficult to teach. The 'learning curve' to independent practice may be longer than previously considered."

https://link.springer.com/article/10.1007/s00192-015-2853-

https://www.medicalprotection.org/uk/for-members/news/news/2018/07/12/use-of-mesh-important-update

5.8.9 STM believes NICE needs to revise guidance CG171 including a full list of defined mesh complications incorporated into standardised informed consent forms and processes. This will minimise lack of informed consent and gaslighting experienced by patients. It will also increase knowledge of mesh complications amongst GPs and surgeons so that mesh injured patients are not sent down an inappropriate care pathway or none at all (as many members of STM have experienced).

5.8.10 Some manufacturers information leaflets have already been amended in the last year and these leaflets list many of the complications described in this submission. Any new patient consent form for mesh should include these as a checklist. Other interested parties should also be consulted on additional contents of the list, for example, patient support groups such as STM and professional bodies.

5.8.11 All medical professionals are required by both their NHS employers and the professional bodies to which they belong, to take responsibility for their Continuing Professional Development (CPD). Surgeons involved in implanting mesh will not be able to obtain informed patient consent if they are not aware of complications. STM are appalled at the apparent lack of knowledge of serious complications amongst those implanting mesh.

5.8.12 STM is aware that the majority of urologists and urogynaecologists do not have the necessary skills or experience to perform the traditional Burch Colposuspension procedure. Many women report not being offered colposuspension or any other traditional repair option. If women were informed about standard repairs they were told that mesh was the best option as it was less invasive and a 'quick fix' compared to standard repairs with longer recovery

times. Yet this procedure has been proven to be as effective as mesh, but without the added complications of mesh. As an employee of a healthcare communications agency quoted to STM, “many leading urologists in this area don’t want to see a “backward step” towards very invasive, surgical options such as colposuspension.” This may indicate why there have been failures in informed consent to enable women to consider all options. STM’s position is that bias towards mesh needs to change in the medical profession and resources allocated for more surgeons to be trained in standard repairs including colposuspension.

5.8.13 STM believes there is an urgent need for NICE, RCOG, BSUG, BAUS and other relevant institutions to identify what resources women, clinicians, and health services need to comply with the Montgomery ruling for informed consent relating to mesh and other standard repair options. Training and educational materials must be fit for purpose. Consultants inserting and removing mesh urgently need guidance.

5.8.14 STM would like to highlight paragraph 87 in the Montgomery judgment as follows:

> “The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.
> 'The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.”

The STM position is that any “reasonable person in the patient’s position” would attach significance to the risk of serious life changing complications for example chronic pain, dysperuenia, loss of sex life. Many women were not informed of these risks. A useful discussion on the Montgomery ruling can be found here:
https://www.bmj.com/content/357/bmj.j2224

5.8.15 In addition in May 2017 an article in the BMJ stated, “In practical terms, the ruling should apply at least back to 1999, when Montgomery saw her obstetrician. Guidance in effect at that time from the GMC, BMA, NHS, and the Scottish Office, supported a doctor’s duty to disclose relevant information and risks. So the Montgomery principles have been known—or should have been known—by doctors for many years.”

https://www.bmj.com/content/357/bmj.j2224

5.8.16 Lack of informed consent is further highlighted in a recent study of 289 elective cases that were analysed across the majority of Scottish hospitals across three surgical specialties (general surgery, urology and orthopaedics.) The clinic consent rate was 27 per cent, while a copy of the documented discussion was only provided to 4.2 per cent of patients. On the day of surgery, the benefits, risks and alternatives to the planned procedure were discussed in less

than half of cases. Clearly there is an urgent need to review the informed consent process and to hold surgeons more accountable as demonstrated in the UK supreme court case Thefaut v. Johnston (2017). This case clarifies and extends the Montgomery ruling of the UK Supreme Court suggesting that a much higher standard for consent for elective surgery is required.

https://www.thesurgeon.net/article/S1479-666X(18)30114-8/fulltext
https://www.researchgate.net/publication/318831309_Thefaut_v_Johnston_2017_A_game_changer_for_consent_in_elective_surgery

5.8.17 Recently RCOG and BSUG issued a joint statement in support of the NICE draft guideline on SUI and POP.

The NICE draft guideline states, "In the cases where it is agreed to use surgical mesh/tape, women must be fully informed of the risks and should be offered a follow up appointment within six months following surgery."

RCOG and BSUG's response states, "We particularly welcome the emphasis on providing women with the support and information they need about all treatment options. This is to ensure they can make informed decisions about the best treatment for their individual circumstances."

"The RCOG and BSUG are dedicated to ensuring the safety of non-surgical and surgical treatments for women."

https://www.rcog.org.uk/en/news/rcogbsug-statement-on-draft-nice-guidance-on-sui-and-pop/

5.8.18 Nowhere in the NICE draft guideline does it provide convincing evidence that women will be fully informed with information of all risks relating to mesh. It is vague on informed consent and communication to the patient of specific additional risks related to the mesh sling procedure, except for surgeons to tell the patient that mesh is a permanent implant and difficult to remove. STM does not agree with the vague term 'discuss' the risks and benefits as this allows room for surgeons to be selective in discussing risks or downplaying risks of mesh. The proportion of women affected by mesh must be defined in numbers with the scientific references. Without this information a surgeon cannot give fully informed consent. Leaving doctors to communicate risks without stating precisiely what these are, is likely to lead to history repeating itself i.e. lack of informed consent and a continuation of the mesh tragedy.

5.8.19 STM believes the list of standardized mesh complications that occur immediately after mesh insertion or in the longer term should be included in the draft NICE guideline as part of the informed consent process, including:

- Dyspereunia
- Partner injury or pain (penile caused by exposure of mesh in vagina))
- Loss of sex life (result of dysperuenia)
- Vaginal bleeding, discharge
- Bladder - recurrent urinary tract infections, incontinence, OAB, retention and voiding difficulties
- Neuromuscular problems – weakness in legs/pelvis, disability (caused by nerve damage/irritation)
- Acute and/or chronic pain in the inner groin, buttocks, lower back, inner thigh, leg, feet, perineum, pelvis, abdomen (caused by nerve damage/ irritation)
- Severe and chronic pelvic pain when sitting down/walking (caused by nerve damage/ irritation)
- Bowel - pain, bleeding, mucus, incontinence, constipation
- Auto immune conditions*
- Fibromyalgia
- Anxiety and depression
- PTSD
- Oedema (legs, feet)
- Swollen abdomen (bloating)
- Paresthesia (itching, pins and needles)
- Skin rashes
- Hair loss

* Lupus, Sjorgren's Syndrome, Psoriasis, Polymyalgia rheumatica, thyroid

5.8.20 There needs to be a lifetime follow up of women inserted with mesh, not just 6 months. This is essential for data collection given scientific and patient evidence that multiple mesh complications occur years after insertion. Recording data for a mere 6 months post-surgery will not capture all women with mesh complications and the data will not tell the true story of complications. Lessons are not being learned. In light of the above, how can RCOG and BSUG state they are dedicated to ensuring the safety of women undergoing mesh surgery?

5.8.21 Going forward, any woman to be exposed to mesh implant risk must be made aware of the true complication rate, for fully informed consent under the Montgomery and Thefaut ruling. The only way this can be achieved is via a retrospective audit through a national recall. This enables women to be informed of the success rate, the failure rate and the complication rate of mesh, for example, mesh exposure, erosion, infection, chronic pain and dyspareunia. Without this information the informed consent process is incomplete.

## 5.9 Misinformation in NHS information leaflets

5.9.1 While there has been a flurry of activity in the past year by the relevant medical institutions to rush out patient, GP and surgeon information and guidance leaflets on pelvic mesh complications, the misinformation and lack of informed consent carries on in practice to this day. STM members have also observed out-dated NHS information leaflets on pelvic mesh that are still on display in hospitals.

5.9.2 In December 2017 NICE issued guidelines that transvaginal POP mesh should only be used in a research context. As far as STM is aware there is no upcoming research therefore it is an effective ban. Even if any research is being conducted then transvaginal POP should have a research information leaflet that has been approved by an ethics committee with a trial protocol and properly stating risks. There appears to be no evidence of this. The NHS V12 POP leaflet simply states that POP mesh is the commonly used gold standard treatment for prolapse with no mention of the risks in the latest guidelines by NICE. This leaflet needs taking off line as a matter or urgency given that:

i. This leaflet still recommends the benefits of POP mesh despite NICE urging caution on trans-abdominal and banning vaginal POP.
ii. NHS Scottish Working group said POP mesh should be restricted and only used in an MDT setting.
iii. RCOG has stated that POP mesh is acceptable.
iv. NHS is caught in the middle of all this conflicting information and the public is being misinformed.

5.9.3 At the time of writing the NHS V12 POP information leaflet is still available online for surgeons to download and print for use in clinic. It was last updated in October 2017. Dr Wael Agur completed work on it in 2014 and he confirms the 2017 revised version has not been updated since 2014. It provides information for patients about prolapse operations. https://www.england.nhs.uk/wp-content/uploads/2017/11/vaginal-organ-prolapse-mesh-leaflet-v12.pdf

STM alerted Lord O'Shaughnessy in a recent meeting in June 2018 to this careless error.

5.9.4 The following NICE audit data form is provided for clinicians to complete and monitor patients. STM understands that the majority of clinicians do not complete this. In addition it reveals the short-term nature of monitoring for adverse outcomes, which commonly occur years after mesh device implant and complications are therefore not captured.

Cover page | Summary | Data

**Summary of data for single-incision short sling mesh insertion for stress urinary incontinence in women**

This tool helps clinicians using single-incision short sling mesh insertion for stress urinary incontinence in women to review clinical outcomes. Data should be reviewed at appropriate intervals and practice should be changed if the results suggest the need to do so.

The tool contains a data collection sheet containing drop down options and free text boxes. A summary of the data is shown in the tables and graphs below.

| Consent | Number | % |
|---|---|---|
| A discussion has taken place about the uncertainties surrounding the procedure's safety and efficacy | 0 / 0 | % |
| The patient has received written information explaining that there are uncertainties about the procedure's safety and efficacy | 0 / 0 | % |
| Written consent to treatment has been obtained | 0 / 0 | % |

| Outcome measures of benefit | Number | % |
|---|---|---|
| Urinary incontinence score at 3 months | 0 / 0 | % |
| Urinary incontinence score at 12 months | 0 / 0 | % |
| Urinary incontinence quality-of-life score at 3 months | 0 / 0 | % |
| Urinary incontinence quality-of-life score at 12 months | 0 / 0 | % |
| Quality-of-life score (include assessment date) | 0 / 0 | % |

| Adverse outcomes | Number | % |
|---|---|---|
| Damage to surrounding structures including perforations or erosions intraoperatively. Please provide details | 0 / 0 | % |
| Mesh erosions or exposure at 12 months | 0 / 0 | % |
| Post-operative catheterisation of 10 days or more within 3 months | 0 / 0 | % |
| Chronic pain or discomfort since the procedure - assesses end at 12 months | 0 / 0 | % |
| Dyspareunia or other impact on sexual function since the procedure - assesses end at 12 months | 0 / 0 | % |
| Overactive bladder symptoms (new onset) within 12 months | 0 / 0 | % |
| Requirement to remove mesh implant between 0 - 3 months | 0 / 0 | % |
| Requirement to remove mesh implant after 3 months | 0 / 0 | % |

**Total number of patients: 0**

## 5.10 Misinformation in manufacturer's marketing leaflets

5.10.1 Ethicon Gynaecare TVT marketing leaflets were observed in May 2018 in a NHS Trust hospital patient information leaflet display. The leaflet states "*Safety & efficacy is supported by 17 years of clinical experience"* and describes complications as "*Transitory.*" This is a direct reference to the flawed and conflicted Nilsson 17 year study (see discussions throughout this submission)

5.10.2 Furthermore, in The People of the State of California V Johnson & Johnson; Ethicon Inc 2016, the State's submission had the following to say about J&J's leaflets: -

"II. J&J MISREPRESENTED THE FULL RANGE OF RISKS AND COMPLICATIONS ASSOCIATED WITH ITS SURGICAL MESH DEVICES

30. J&J misrepresented the safety of its surgical mesh products by failing to disclose known risks and complications to doctors and patients, which would have been material information in considering treatment options. For many years, J&J's marketing and promotional materials

purported to provide complete risk information but failed to include significant and/or common risks. For example, the following is a non-exhaustive list of risks and complications missing from the TVT brochures at various points in time:

a. Pre-2008-2008 TVT patient brochures: chronic foreign body reaction, defecatory dysfunction, *de nova* urgency incontinence, detrimental impact on quality of life, dyspareunia, permanent dyspareunia, dysuria, hematoma, mesh contracture, need for removal, nerve damage, pain, chronic pain, pain to partner during sex, permanent urinary dysfunction, recurrence, sarcoma (cancer), urinary tract infection, vaginal scarring, and worsening incontinence;

2008-2011 TVT patient brochures: chronic foreign body reaction, defecatory dysfunction, *de nova* urgency incontinence, detrimental impact on quality of life, permanent dyspareunia, dysuria, hematoma, mesh contracture, need for removal of the device, nerve damage, chronic pain, permanent urinary dysfunction, recurrence, sarcoma (cancer), urinary tract infection, and worsening incontinence; 2011-2012 TVT patient brochures: chronic foreign body reaction, defecatory dysfunction, *de nova* urgency incontinence, detrimental impact on quality of life, permanent dyspareunia, dysuria, hematoma, mesh contracture, need for removal, pain, chronic pain, permanent urinary dysfunction, sarcoma (cancer), vaginal scarring, and worsening incontinence.
J&J's marketing and promotional materials for its other SUI mesh devices, and its

31. POP mesh devices, similarly misrepresented product safety by concealing known risks and complications.
32.material risks in its informational, educational, and training materials directed to doctors.
33. As a result by 2012, over two million women had undergone treatment worldwide without being warned by J&J of the serious risks and complications associated with the device, and the debilitating impact it could have on a woman's quality of life."

**"**V J&J MISREPRESENTED THE SEVERITY AND FREQUENCY OF THE COMPLICATIONS:
43. For the complications that it did disclose, J&J misrepresented the severity and frequency of the complications associated with surgical mesh. For example:

a. J&J made false and misleading statements in its marketing, promotional, informational, and educational materials about complication rates of mesh, citing to studies that did not actually support the propositions they were cited for.
b. J&J knowingly cited to studies for which results were scientifically questionable due to study design and/or conflicts of interest. For example, J&J used the result of the Ulmsten study to sell its SUI products when J&J had (1) purchased the rights to the SUI device from Dr. Ulmsten and (2) contractually agreed with Dr. Ulmsten that he would only get paid a specific sum if his study produced favourable results regarding the product.

44. Millions of women were implanted with surgical mesh without knowing the full risks of the decision because the company misrepresented (1) the full range of possible complications; (2) the risks that surgical mesh poses, which are not present in the alternative non- mesh repair; and (3) the frequency and severity of the risks that it did disclose."

https://oag.ca.gov/system/files/attachments/press_releases/J%26J%20Complaint_1.pdf

## 5.11 Patriarchy and institutional denial of mesh injured women in pain

5.11.1 STM's experience is that the history of the mesh scandal is riddled with the misdiagnosis and mistreatment of many women. Mesh injured women seeking diagnosis for their chronic pain have all too frequently been dismissed, and actively harmed by perceived gender bias. Dismissive attitudes women have faced from male doctors is far from unusual. Women have spent years searching for a doctor who would take their unexplained chronic pain seriously. There are regular reports by STM members of male doctors disbelieving them and treating them as less than human, not listening to them and even referring them for psychiatric treatment.


5.11.2 STM's view is that mesh-injured women's journeys to treat their chronic pain, exposes a persistent patriarchy, where they have often been told it is all in their head. Some women doctors also contribute to the patriarchy by putting women patients down with their

dismissive attitudes. Women's experience on STM is that they are often expected to comply with the recommended treatment plan, even if they do not fully understand it. Mesh injured women have had to become tireless advocates for themselves, taking on the task of learning everything they can about their pelvic mesh health issues, to speak the language of their doctors, and to persist until they are heard. Often doctors become impatient or rude if too many questions are asked or their judgement is questioned. Many STM women have resorted to taking their partners or husbands with them to appointments to verify their pain or cause of pain, before doctors have taken them seriously. STM believes there needs to be a change in the doctor-female patient relationship where the principle of patient autonomy is respected.

5.11.3 A STM survey, 2017, reveals that 85 per cent of respondents were told their mesh implant had nothing to do with their chronic pain. Many STM members with chronic pain and poorly understood complications from pelvic mesh devices including chronic fatigue, dyspareunia and fibromyalgia go through this every single day. In the STM survey, 560 out of 564 STM respondents reported complications from mesh with almost 80 per cent suffering from chronic pain due to erosion into other organs (28 per cent); nerve damage (57 per cent); fibromyalgia (27 per cent); autoimmune disease (25 per cent) and 61 per cent suffering anxiety and depression, including PTSD. Up to 40 per cent of respondents had their mesh implanted up to 10 years ago; 23.5 per cent up to 5 years ago; 8 per cent up to two years ago and 6 per cent less than a year ago.

5.11.4 The very recent Oxford study published by Goodall et al, September 2018, titled 'Outcomes after laparoscopic removal of retropubic midurethral slings for chronic pain,' states that, "Patients may attribute highly diverse symptoms due to mesh insertion, including chronic pelvic pain, chronic fatigue, fibromyalgia and pain distant from the pelvis. There is limited evidence to support the causality of mesh in these distant symptoms. Patients may also have psychological morbidity rooted in anxieties about long- term harm from mesh." STM finds the latter sentence dismissive of women presenting with symptoms distant to the pelvis. A number of STM members have reported fibromyalgia and inflammatory/autoimmune symptoms since mesh insertion. Given there is a dearth of research linking these symptoms to mesh, STM believes it is inappropriate to indicate symptoms may all be in women's heads.


5.11.5 In a recent press release, Dr Andrew Baranowski, President of The British Pain Society states, "Put simply, living with chronic vaginal pain is associated with a significant negative effect on mood, thoughts, behaviour, sexual and personal relations as well as employment…It increases the risk of depression and anxiety and is associated with increased suicidal risk as well as mortality from other conditions like cardiac problems." It is therefore shocking for STM to hear how many women members have been badly treated by their GPs and consultants. Box 7 illustrates some of the comments reported by STM members from their GPs or consultants that illustrates evidence of 'gaslighting.'

5.11.6 Significantly the British Pain Society also stated, "Of the 99,000 patients who are recorded in Hospital Episode Statistics as having had these surgical procedures, 9.8 per cent had a subsequent hospital admission. More will have visited their GP or other NHS services. It is not clear how many women develop severe levels of chronic pain - according to some estimates, it could be up to 40 per cent. Research is urgently needed to fully understand the extent of this problem." Their view supports the STM position that complications have been significantly under recorded and under reported by mesh Consultants. (Annex 9)

5.11.7 Women experiencing transvaginal mesh failure symptoms experience recurrent vaginal, bladder and kidney infections. In some cases, these infections are the result of the continual irritation and inflammation caused by the mesh. In others, infections are the result of perforations or erosion of mesh into the vagina and bladder. In transabdominal mesh failure, infections result from perforation of the bowel. Some STM members have become antibiotic resistant. STM questions to what extent mesh-injured women with repeated bladder, bowel and kidney infections are at risk of antibiotic resistance, potential renal failure

**Box 7: Responses from GPs and consultants when STM women have complained of mesh related pain.**

“I was told it was all in my head and needed to see a psychiatrist. They even made me an appointment.”

“When I went back after TVT & double prolapse repair op in '08 with a gaping perineum & constant UTI's, thrush & cystitis, one of my surgeons said I needed to learn to wipe my bottom properly - front to back - as I was obviously infecting myself!”

“He actually got cross with me when I was saying it was the Mesh. He shouted at me saying that the surgeon who put it in me was very a brilliant surgeon. My reply was I never said he wasn’t it was the product.”

‘It’s your emotional state that’s causing your pain’

"Its just period pains.... oh dear! Its definitely not the tape because its really tiny and no where near your groin" AND... "Stop watching Sky news" AND... " You must have a low pain threshold. "

“You’re obese, lose weight and your symptoms will go.”

“At the GP after night-time faecal incontinence started: "Many young women are quite highly strung, I'm not sure what you want me to do for you, have you tried yoga or CBT?"

“My implanting surgeon recommended the "paper thin teeny weeny bit of tape, so simple even my husband could put it in for you and he's not even a doctor!’ Then when I returned to her in agony using a crutch to walk I said, ‘I've looked into this, is it

and sepsis. Are appropriate monitoring and care pathways in place? Is related data being gathered and analysed? This is particularly relevant given the recent death in Scotland of a woman who died of sepsis and organ failure with an underlying cause of death due to perforation of her bowel associated with sacropolpopexy mesh failure.

https://blogs.bmj.com/bmjebmspotlight/2018/09/10/first-do-no-harm-surgical-mesh/

**Women pay the price for mesh innovation**

Professor Bernard Jacquetin, is a former gynaecologist surgeon in France, who created the mesh Prolift device from the Johnson & Johnson laboratory that was removed from the market in 2012. According to Jacquetin, women, in a way, have paid the price of innovation:

"*It should not be said that they paid, but it's sure there's a bit of that ... We have to start on women, it's not the corpse that will tell us she is fine with our prosthesis or not*.'

https://translate.google.co.uk/translate?sl=fr&tl=en&u=https%3A//www.nouvelobs.com/rue89/nos-vies-intimes/20171019.OBS6222/prothese-qui-cisaille-le-vagin-9-medecins-francais-aux-regrets-variables.html

## 5.12 Dyspareunia being ignored

5.12.1 Pelvic mesh complications is a *taboo* women's health topic and is only being brought to light because of the persistence of campaigners like STM who have been brave enough to share their embarrassing personal stories to get this issue highlighted. Institutional denial makes it so much worse for those suffering pelvic mesh complications. One example is dyspareunia (pain during intercourse and loss of sex life - see Box 8.)

5.12.2 The 2003 study by Yeni et al published in the International Urogynaecology Journal found that both SUI and the TVT procedure negatively affect sexual function in women. The study recommended women should be counselled about this. An STM survey in 2017 found that 72 per cent of respondents reported suffering from dyspareunia. Yet none of the STM members report ever being informed about this risk. Dyspareunia has not been included in the informed consent process prior to mesh device insertion or, until recently, in the information literature.

https://www.researchgate.net/publication/8958225_The_effect_of_Tension-Free_vaginal_Tape_TVT_procedure_on_sexual_function_in_women_with_stress_urinary_incontinence

**Box 8: Responses from GPs and consultants when STM women have complained of mesh related pain during intercourse or loss of sex life.**

"After me telling my GP (past) I hadn't been intimate with my partner for 6 years as it was too painful, he printed out an online brochure for a device to make me "feel tight and wanted again."

"When I went back to my implanting surgeon as the mesh had cut my hubby she said it can't possibly be the mesh you must have something else sharp in there!"

"I was referred back to Gynaecology by my GP due to an inability to have sex with my husband (2 years+) because of worsening pain. The Gyny Registrar said it was most likely adhesions, which were difficult to treat. He gave me a prescription for a cream to insert (prior to trying to be intimate) which he said would help. My GP then telephoned me to query the prescription as it was a local anaesthetic."

"The problems are more likely to be due to you having a tight vagina and a lot of women would be very jealous of your tight vagina"

"At a follow-up meeting with the surgeon, when I tearfully complained of painful sex, the surgeon said," but he can enter you, can't he?"

"One doctor in A&E even told me, "Lucky girl, you now have a designer vagina!"

*Source: Comments shared on STM Facebook forum*

5.12.3 NHS England appears to give a psychological explanation for long-term pain during intercourse. Recommending psychosexual counselling puts the blame and onus back on the patient. In NHS England's current guidance for dealing with dyspareunia they make the following statements:

***'Long-term pain in the vaginal area, at the site of the tape insertion or during sexual intercourse (due to vaginal scarring).***

*Where pain is experienced during intercourse, physiotherapy can **help in the stretching of scar tissue** and using 'trigger-point techniques' can relieve the pain or referral to a pain management team. Advice can be given regarding care of the vagina after surgery and, if necessary, referral for psychosexual counseling.'*

5.12.4 In the above statements there is no mention of mesh erosion/protrusion through the vaginal wall, only vaginal scarring, causing pain during intercourse. Also no warning that the sexual partner can be injured by mesh that has protruded through the vaginal wall.

5.12.5 The data presented by STM members highlights the failure in appropriate recognition of the risk and treatment of dyspareunia by the medical profession. There is an urgent need for an end to institutional denial of pain caused by mesh erosion through the vaginal wall often causing infection, not just scarring. This issue needs to be addressed in the NHS England patient information leaflet and the ongoing revision of NICE guidelines CG171 given the scope for review of guidance includes:

*'Assessing complications associated with mesh surgery for stress urinary incontinence or vaginal organ prolapse'.*

*'Managing complications associated with mesh surgery for stress urinary incontinence or vaginal organ prolapse.'*

5.12.6 There is no code and therefore no data for incidence and outcomes of treatment for dyspareunia at all and caused by a) mesh erosion/protrusion through the vaginal wall and b) scar tissue, in the HES episode statistics and other reporting systems by professional bodies such as BAUS.

5.12.7 The Box 9 case studies (and Annex 7 case study) illustrates the negative impact on women's quality of life due to dyspareunia, loss of sex life and other complications of mesh. Significantly, it highlights the denial or ignorance of doctors in treating women with complications. The data presented by STM members highlights the failure in appropriate recognition of the risk and treatment of dyspareunia by the medical profession. There is an urgent need for an end to institutional denial of pain caused by mesh erosion through the vaginal wall, not just scarring, that causes dyspareunia. A 2017 STM survey revealed that 15 per cent lost their marriages or primary relationships due to mesh and a further 54 per cent reported strain on their marriage or partnerships. STM women have shared their stories of relationship and marital breakdown, leading in some cases to families being torn apart due to dyspareunia, loss of sex life and related mental health problems. These symptoms have taken an immense toll on women (and their partners and families), emotionally, socially and physically, yet dyspareunia and its causes is lacking from the medical guidance literature and reporting systems on mesh complications and adverse events. For example, the York report, 2012, produced for the MHRA did not include dyspareunia and loss of sex life in its risk statistics.

5.12.8 Evidence of similar dismissive attitudes by consultants towards women's lost sex lives was examined during the Australian federal court class action against Johnson & Johnson in 2017.

https://www.theguardian.com/australia-news/2017/aug/28/pelvic-mesh-victims-disgusted-at-suggestion-of-sodomy-as-solution

**Box 9: STM Members' Successful Post-Mesh Removal**

'I thought I'd give an update. I'm 10 weeks post full mesh removal and haven't felt this well in years! My TVT was put in nearly 14 years ago and I thought it was wonderful and I didn't get any of the pain or problems that many of the ladies here have experienced. My story was one of feeling increasingly unwell over a 5 year period, I gave up my job as I couldn't cope and lived everyday with fibromyalgia. I had constant UTI's, terrible urge incontinence and vaginal infections, my IBS was awful and I dreaded my period coming, intimacy was impossible and had been for years. I was treated for menopause but nothing helped and was tested for Sjogrens. After watching Sky News last August with my husband my eyes were opened to a possible cause. Fast forward to January and I saw (consultant) who said my tape was likely to be the cause of my problems and that it has shrunk and was now against my urethra. In surgery it was found that my TVT was massively infected and all the area inflamed, despite no erosion to create such an infection. I also had a giant cell response. 10 weeks on my fibromyalgia is in remission, menopause symptoms gone, my head is clear and I have more energy than I've had for 10 years. Inflammation markers are down and I am looking to start exercising and planning to learn a new sport. I'm not 100% continent but I'm being referred for physio and I can live with it as it's nowhere near as bad as the urge incontinence before! I'm still being careful to not lift anything too heavy but I am finally pain free, mesh free and looking forward to the future. So for any of you ladies who are years down the line, keep a check on things, listen to your body and get your mesh checked out if you suspect anything is wrong. I've learnt it isn't always a bad surgeon, this mesh changes and our bodies react to it! I wouldn't be where I am without this group giving me information to get removal and finally get well again. I know some of my issues are not reversible but I feel so much better. Xx'

'My mum finally had her sling removed at Leicester General hospital four weeks ago. She's still tender and taking it slow but...the excruciating pain in her hips has gone, the swelling she had in her ankles has disappeared, she's come off bladder control and blood pressure tablets, the discharge has gone, blood pressure back to normal, no more boils in groin, no more soreness and itching and balance is better...all caused by this damn awful mesh. She's a new woman - but it is shameful that she's had to suffer since 2010. The relief is palpable. I'm so proud of her for fighting for her appointment.'

*Source: Comment shared on STM Facebook forum, 2018*

## 5.13 Flawed monitoring in healthcare system hides the truth

5.13.1 From the outset, the lax attitude of the medical profession in rigorous monitoring and evaluation of medical devices is evident. For example, the Oxford Radcliffe Hospitals (ORH) NHS Trust began using the Ethicon TVT device procedure for SUI in January 2000. Until 2003 its performance of the procedure was not monitored at all. The ORH Trust undertook a first retrospective audit in 2003 of its performance of the TVT procedure in 95 patients, in order to determine whether its patient care was fully compliant with the 2003 NICE guidelines for TVT. At the time of the audit, the average period of time that had elapsed since the procedure with patients was 20 months. Since it is known that onset of mesh complications can occur years after insertion, many of these women may not have had symptoms caused by mesh erosion to report. Only 71 per cent of women received full information about the TVT operation before signing their consent to it. The content of the 'full information' is unknown, but it is unlikely that all the risks were described in the consent process, for example chronic pain, dyspareunia, erosion into organs.

5.13.2 The Oxford audit reported the overall picture of findings from the audit was generally satisfactory and reassuring, with no major problem areas identified (see below for complications investigated.) Missing from the list is chronic pain; dyspareunia/loss of sex life; erosion of implant into other organs – bladder, bowel, vaginal wall. Lack of systematic long term monitoring and evaluation of all complications means the medical profession has not recorded the outcomes of vaginal medical devices.

**ORH NHS Trust 2003: Summary of TVT complications found**

| **Objective** | | **Literature Standard (Stanton et al)** | **Audit Result** |
|---|---|---|---|
| The prevalence of intra- and post-operative complications with TVT is comparable with that achieved by current best practice reported in the literature (Stanton et al*) | 1 Perioperative bladder / urethral perforation | 5% | 4% |
| | 2 Bleeding | 1% | 1% |
| | 3 Failure to void urine post operatively | 10-20% | 27% |
| | 4 Long term voiding disfunction | 1% | 2% |
| | 5 Tape rejection | 0.1% | 0% |

| | | |
|---|---|---|
| 6 Defective healing | 0.1% | 0% |
| 7 De novo urinary urgency | 10% | 12% |

*S L Stanton and P E Zimmern (2003), Female vaginal Reconstructive Surgery, Springer Verlag London, ISBN 1852333626

https://pdfs.semanticscholar.org/6a03/4e36e3b26b90d3d5a185f7e862e2f2fa7bc7.pdf

5.13.3 The Review mentions trust between patients and medics: "*The trust between patients and the healthcare system is extraordinary and precious, it is what keeps the country healthy and keeps the NHS close to our hearts. That trust, though, is also fragile"*. Many STM members feel there has been a gross abuse of trust, and this must be recognised and addressed. The following statements serve to further weaken trust:

"*The issue is not the product, but clinical practice*. *That's what's going wrong.*" Jackie Doyle Price, Junior Health Minister, vaginal mesh debate, House of Commons debate on vaginal mesh, October, 2017.

"*Widespread media reports that the mesh breaks down within the body are false."*

Statement issued by Oxford CCG, January 2018, on behalf of Simon Jackson Urogynaecologist, Oxford and colleagues.

5.13.4 STM is aware that the literature suggests otherwise with evidence of various degrees of degradation in the chemical structure of polypropylene resulting in the loss of structural integrity through the material becoming brittle. Both the product AND clinical practice involving incorrect insertion of mesh devices are the issues that need to be investigated.

5.13.5 The English and Scottish mesh working group TORs failed to include the science of mesh implants. They also failed to include how transvaginal SUI mesh implants are inserted blindly through a clean contaminated field, using hooks that are classified high risk in USA owing to high risk of injuries. These groups were formed to provide solutions for mesh-injured women. The latter has still not been achieved despite the establishment of groups five years ago in 2013.

5.13.6 STM believes that it is not safe to continue pelvic mesh trials in women. At a minimum STM believe the following concerns should be addressed:

i) Check that all women involved in mesh trials are aware of the current suspension of mesh, that any complications which occur during the trial are reported to the MHRA as well as to trial administrators; that all participants get a specific questionnaire which includes adequate questions about post operative incidences which affect quality of life, for example, pain in groin, vagina, hips, buttocks, legs, thighs, dyspareunia, erosion and voiding difficulties causing UTIs.

ii) The Review Team should request a clinical audit to be commissioned of all ongoing mesh trials, to determine whether complications that have arisen so far mean the trials should be terminated.

iii) The Review Team should write to the ethics committee regarding: the SIMS, VUE and PROSPECT mesh surgery trials to ask them why the trial or the interim 2 year results have not been published in light of the current safety concerns and suspension of mesh.

iv) Ensure that all trial participants and their GPs are aware of the specialised centres for mesh removal so that mesh can be removed as soon as significant problems occur or worsen. It should be considered that tissues and nerves weave through mesh within six weeks of implantation, which makes it very difficult to remove. As MHRA states in its October 2014 report summarising the evidence on the benefits and risks of vaginal mesh implants, 'Vaginal mesh implants are permanent implants that are not designed to be removed.'

## 5.14 Costs to NHS of medicating mesh-injured women

5.14.1 The significant costs of the pelvic mesh scandal to the NHS are missing in the literature. Actual annual costs of prescriptions from a sample of STM members, covering before and after mesh removal, shows the actual costs are significantly higher than the NHS annual 2015 average cost prescription per head of £169.14. See Box 10 for details. A woman taking medications for complications of mesh over a 5 year period can amount to over £11,000 (additional costs include multiple GP and hospital consultations; scans; blood and urine tests; endoscopy; nerve conduction tests; proctogram, physiotherapy and surgeries.) Many STM members have had multiple surgeries to partially remove mesh followed by full removal of mesh and a third procedure for incontinence (Burch colposuspension or autologous sling). Each surgery costs around £8,000. Women often need to attend a pain management programme at a cost of £15,000. Many women suffer anxiety and depression and some have been diagnosed with PTSD representing additional costs to the NHS; and many women in desperation have paid for private treatment. These costs indicate the need for the NHS to urgently provide a full cost benefit analysis to prove to the public that pelvic mesh devices for SUI, prolapse and ventral rectopexy are a cost effective treatment option.

### Fig 1: Cost analysis of Prescription Drugs by Sample of Mesh Injured Women

| STM Individual Members Costs analysis | Monthly actual prescription cost per head range | Annual actual prescription cost per head range |
|---|---|---|
| Complications after mesh implant | £79 - £186 | £948-£2,232 |
| After full mesh removal | £60 | £720 |

## Addendum to STM Submission

**Addendum to Action 5. Review the governance, accountability and effectiveness of the medical profession**

5.2.2 What is clear from STM's own research is that the device regulation system in the UK is in dire need of an urgent overhaul. APHI, the body representing device manufacturers in the UK, has stated that one of their roles is to "Influence the regulators both in the UK (MHRA) and at European level." This is to ensure any revision in policy remains "industry friendly." APHI has stated they support "Policies that support the rapid evaluation, reimbursement and adoption of medical technologies by UK healthcare systems." The key word here is rapid. This is also a major concern for STM since rapid access cannot be easily combined with safety, if indeed it can at all. STM is concerned that, in the event of Brexit, any new Post- Brexit legislation and tightening of the device regulation system in the UK, to improve safety relating to medical devices, should not be influenced by heavy lobbying by industry. Engagement needs to include patients and doctors.
https://www.mediwales.com/login/uploaded/ABHI%20and%20MediWales%20Briefing%20Event%20full%20slides%20.pdf

# Action 6. Improved processes to enable mesh affected women to access fast-tracked quality assured multi-disciplinary services for full mesh removal surgery

## 6.1 Lack of access to quality healthcare for women with mesh complications

6.1.1 Many mesh injured women have been frustrated at being misdiagnosed or ignored by their GPs and/or consultants when presenting with mesh related symptoms, sometimes for many years. As a result they suffer emotionally, socially, physically and economically. Many women on STM have reported having to stop working; take strong medication for chronic pain; suffer mental health illness; become disabled and house-bound; strain on other family members; suffer marital breakdowns and lose their homes.

6.1.2 Pelvic mesh complications is a *taboo* women's health topic and is only being brought to light because of persistence by campaigners like STM who have been brave enough to share their embarrassing personal stories to get this issue highlighted. Institutional denial, bias in medical treatment, gaslighting and humiliation of patients, makes it much worse for those suffering vaginal mesh complications. One example is dyspareunia (pain during intercourse) and loss of sex life caused by erosion of pelvic mesh through the vaginal wall.

6.1.3 In desperation a significant number of STM women have spent money they can ill-afford on travel and private treatment. Around the country there are few knowledgeable consultants able to give a correct diagnosis and pathway to speedier treatment for mesh complications and full removal. This situation is due to the referral system from GP to consultant being ineffective as the GP or consultant has too often denied symptoms are linked to mesh complications. A number of women have spent their savings on private surgery with the few

knowledgeable consultants for mesh removal, as they had given up on the NHS after years of being ignored. A full retrospective clinical audit could inform improvements to the NHS diagnosis and referral process.

6.1.4 STM is concerned there are few experienced surgeons in the UK who are skilled in full mesh removal. Each case is different, with women often presenting with multiple complications and an unknown number of cases will require more than one surgeon to work as a multidisciplinary team to successfully remove mesh. NHS waiting lists with the handful of skilled surgeons in UK to remove mesh are too long, while women's complications worsen. Hence why women are desperate to seek private treatment as a result.

6.1.5 STM's experience is that women present with multiple symptoms over time and often these are not linked to mesh. The Petri et al study analysed different complications of synthetic suburethral slings. Between 2003 and 2010, 359 cases directly related to complication of synthetic slings in female SUI were surgically managed. Over 50 per cent of women in this study developed new onset or worsening of symptoms of overactive bladder (OAB). The next common complication seen in the study was development of lower urinary tract obstruction, which accounted for 48 per cent of women. The third most common complication was vaginal exposures that accounted for almost 19 per cent and pain at the operation site (groin or thigh pain in the case of the transobturator route, and vaginal or pelvic in others) accounted for 14 per cent of women. Another observation was that 10 per cent of patients with TVT (by the retropubic route) presented with long term pain compared to 34 per cent of patients undergoing sling surgery by the trans-obturator route. Dyspareunia was seen in 6 per cent of women with complications. Infection of sling material accounted for 10 per cent of complications. In this study only 35 per cent of patients with sling complications had isolated symptoms. This means that around two thirds of patients with complications present with more than one coexisting condition (for example de novo urgency and vaginal exposure, obstruction and pain). Most of the complications were seen between one and five years after insertion of slings.https://www.ncbi.nlm.nih.gov/pubmed/22944381

6.1.6 In a BSUG newsletter from 2017 there is mention that a mesh removal centre is not an endorsement of competence. It just means they meet set criteria.

https://bsug.org.uk/budcms/includes/kcfinder/upload/files/BSUG%20news%20letter.pdf

6.1.7 It is therefore critical that NICE provides comprehensive guidance on specifications for accredited mesh removal centres as a priority and that they are adequately resourced by a multidisciplinary team of experienced clinicians to enable women to better access appropriate care in the UK.

6.1.8 In the event of a continuation of mesh use, placement of surgical mesh should only be performed by surgeons with the requisite knowledge, accredited surgical skills training and experience in pelvic reconstructive surgery. Different mesh kits demand different skills and specific training. NICE needs to ensure standards of training and level of experience are made clear for all mesh procedures including insertion, partial and full removal. STM's position is that revised guidelines CG171 should not be finalised until the outcome of this Review.

**Myth #9 – *"It's bad doctors who had the complications, not the good doctors."***

**Fact:** This defies logic. With 100,000 plus lawsuits filed in the USA- are there that many bad doctors? During the ***Linda Gross v. Ethicon*** trial in February 2013, Ethicon did note that some of the doctors taking weekend cadaver clinics hosted by Ethicon and Gynecare, a division of Johnson & Johnson, were not catching on as fast as the Top Tier docs. See Linda Gross Trial Day 19 reference below. If a product cannot safely be used in the hands of a medical doctor and the company knows this, why would it continue to market the product to them anyway?

https://www.meshmedicaldevicenewsdesk.com/top-10-myths-woman-are-told-today-about-pelvic-mesh/https://www.meshmedicaldevicenewsdesk.com/day-19-linda-gross-v-ethicon-medicine-and-marketing/

## 6.2 Pelvic floor physiotherapy and pain management is under resourced

6.2.1 An important treatment option that is too often not offered or available to mesh injured women is pelvic floor physiotherapy. Women who have had partial pelvic mesh removals and/or who are awaiting full pelvic mesh removals can benefit hugely from pelvic floor physiotherapy to address vaginal floor dysfunction with a wide variety of interventions needed including; vaginal floor assessment and treatment, bladder retraining, lifestyle and fluid advice, advice regarding appropriate exercise participation, pain management and advice regarding voiding. While some women's pelvic floors are not suitable for this treatment due to the scale of internal damage, there are many women who can benefit. This type of conservative treatment option can avoid the need for further invasive surgery after pelvic mesh removal. This option is rarely available in practice. Physiotherapy, biofeedback. and nurse specialist advice can also be highly beneficial in cases of bowel dysfunction. Colorectal nurse specialist advice in particular is not widely available and many women undergoing ventral mesh rectopexy will not have had access to such services before undergoing surgery.

6.2.2 In addition providing all women with systematic access to a first-line conservative treatment option of pelvic floor physiotherapy after birth will reduce the number of women seeking what is often marketed to them as 'quick fix' mesh surgery options (but is actually invasive surgery) for SUI or POP in the first place. The costs of repeated surgeries are likely to far outweigh the costs of providing physiotherapy services. A good example of progress in this area, at least on paper, is the Welsh Care Pathway. STM believes the Welsh Task and Finish Group report into improved community care for women seeking help for SUI or POP is excellent. However in practice there are only two specially trained pelvic floor physiotherapists in Wales. The question remains how NHS Wales is going to meet the action points of sending all women in the first instance to a robust pelvic floor physiotherapy team in their community.

6.2.3 The British Pain Society recommends that women with mesh complications should be supported by trained pain specialists at all levels from their local hospitals up to the new specialist mesh removal centres. Dr Andrew Baranowski, President of The British Pain Society states in a recent press release, "There are probably only five specialised vaginal pain management services in England that would meet NHS specifications to provide specialist

assessment and management of conditions…There are limited NHS resources for those that live with chronic vaginal pain. Many medics struggle to know how best to support and manage those living with it."

6.2.4 According to a RCOG/BSUG 2013 National Urinary Incontinence survey, more than 50 per cent of female patients referred to secondary care are reported not to have received any treatment in primary care (this would include pelvic floor physiotherapy and pain management). Linda Cardozo has stated that treatment is shifting from secondary to primary care. Yet pelvic health physiotherapy and specialized pain management services are vastly under- resourced and need to be urgently addressed across the UK.

https://slingthemesh.files.wordpress.com/2018/03/mesh-surgical-care-for-sui-protocol.pdf

**Box 10: Comments by mesh injured women in pain feeling suicidal**

'My husband and I had this conversation not long ago. We have experienced the trauma and anxiety of not knowing what is happening only to be told it's weight and anxiety causing all the symptoms and pain. As we went to yet another emergency hospital visit in the early hours of the morning I sat crying in the car saying how fed up I was with everything I was feeling and going through just knowing nothing would be done again. Also that this was just one small part that no one saw. The stress and trauma affecting not just me but him too. All the follow on effects to the family and disruption to our lives and work as we are self employed. The ongoing costs of looking for answers causing us financial difficulties. None of this affects the pockets and lives of the mesh pushers.'

'It's so true that our loved ones suffer as well as us. For me my husband was the one to acknowledge my symptoms after watching the Victoria Derbyshire show but doesn't want me talking to others/publicising the issue I'm having. I feel we're drifting further apart and I don't know what to do.'

'I too felt suicidal for a long period. It was only the thought of how much misery I would leave behind that stopped me. Husbands, partners, children and whole families suffer too because of this horrible mesh. '

'12 years ago today and 2 days before my 39th birthday. I had my second mesh fitted. This week has been an emotional roller coaster and it hit me yesterday whilst giving a media interview that this doesn't just affect us but has a massive impact on our whole family. There are things I heard my husband tell the reporter that I was not aware of, or had forgotten. He sobbed as he spoke. He had not opened up to me before as he said I had enough to deal with. I had spent almost a year in and out of hospital. For a long time I was told it was all in my head and was sent to see a psychiatrist. I didn't go at first as I knew I wasn't mentally ill and so did my GP. However after several months I had enough of being ignored and treated appalling by medical staff at the hospital. I couldn't take any more and I attempted to take my own life on several occasions. My husband would get a phone call then drive over an hour home to sort out our children. Make sure someone could look after them as no family are close by. Drive another hour to the hospital and argue with the doctors at the hospital to help me and find a cause for this pain. He had to beg them not to section me telling them I'm in pain not insane. He revealed a lot of other things and as he spoke it upset me and I felt guilty for putting my family through all this. I know I'm not to blame but I still feel the guilt. Mesh doesn't just affect us it us it affects our nearest and dearest.'

*Source: Comments made on STM Facebook forum, 2018*

## 6.3 National specialised commissioning team

6.3.1 STM welcomes the establishment of a task force of interested bodies by NHS England specialised commissioning to define new pathways of care for women with SUI or POP and for those seeking mesh removal. However, STM has not been invited to provide feedback during the consultation period, despite being the largest patient support group in the UK with more than 7,000 members. In addition STM is aware that leading mesh removal surgeons have also not been directly invited to provide feedback. Yet NHS England's guidance on user engagement is supposed to be key in the development of specification.

https://www.england.nhs.uk/participation/resources/commissioning-engagement-cycle/

6.3.2 STM believes it is essential for all leading mesh removal consultants to provide clinical opinion on the costs and benefits to NHS and patients of partial vs. full mesh removal; monitoring and evaluation of symptoms and outcomes presented by patients and quantified; numbers of patients treated in the past 12 months for partial and full removals and outcomes; future data collection and management; length of waiting lists; histology testing and any emerging results so far; opinions on resourcing MDT mesh removal centres and related long-term research; views on translabial scanning as an addition to the current suite of diagnostics; MDT core composition and future treatment strategy.

6.3.3 STM anticipates the Review will seek answers to the following questions from the NHS England task force:

i. How is the service specification being developed and what is the timeframe for completion?
ii. Who is being consulted in the development process of the service specification? For example are leading mesh removal surgeons, translabial ultrasound scan radiologists, pelvic floor physiotherapists, psychiatrists/psychologists, pelvic pain specialists, urinary tract infection patient groups like CUTIC and mesh patient support groups such as Sling the Mesh being contacted directly for feedback?
iii. How are processes being improved to enable mesh-affected women to access fast-tracked quality multidisciplinary services, particularly mesh removal surgery, in all regions of the country.
iv. How can women be reassured that enough surgeons are qualified to undertake full mesh removals competently? STM is aware that currently not all surgeons at mesh centres are experienced in the complicated procedure of full mesh removal.
v. What is being planned to ensure enough surgeons are adequately trained in traditional methods of repairing SUI and POP that do not use mesh devices e.g. Burch Colposuspension and autologous pubovaginal slings (PVS)?
vi. Are resources for women's health physiotherapy, nurse specialist advice and mental health services included in the specification?

vii. How will GPs be trained to recognise mesh complications and appropriately refer patients to specialists?

viii. How will NHS England ensure all consultants are held accountable to report issues with devices to MHRA ?

ix. What is the justification for partial mesh removals as a pathway of care? STM strongly disagrees with the draft specification that states 'simple localised excision' should be a pathway of care. We are extremely concerned about 'non complex' (partial removal), as a significant number of women on STM have had unsuccessful partial removals or 'snips' and continue to suffer from symptoms – partial removal may address some of the problems but generally only n a temporary basis and will not alleviate chronic pain and other symptoms caused by nerve damage or nerve irritation as a result of remaining mesh. Also, STM's experience shows that partial removal of mesh makes it more difficult for surgeons to locate and fully remove mesh when women present themselves again at a later date with ongoing and emerging new symptoms that severely affect their quality of life. Multiple surgeries increase costs to NHS and prolong the suffering for women. Many women want full mesh removals, having been ignored and spent years suffering physically, emotionally, socially and economically.

x. If NHS England is adamant that 'simple localised excision' is an appropriate pathway for some women presenting with chronic pain, then how will fully informed consent be ensured? This must be given both verbally and in writing including the significant risk of existing symptoms not improving, other symptoms developing and likelihood of further surgery to fully remove mesh in the future. STM's experience is that clearly many GPs and consultants have failed to provide informed consent relating to the efficacy and safety of mesh insertion with devastating consequences. Lack of informed consent is a substantial aspect of the pelvic mesh scandal in which 90 per cent of women respondents in a Sling The Mesh survey, 2017, stated they were not given informed consent before surgery, despite the Montgomery Ruling.

xi. In addition, how will robust data management, audit and governance be ensured? STM's position is that it will be vital to ensure robust monitoring systems are in place to monitor outcomes of partial removals and full removals in the longer term. Patients should be monitored for life using a minimum core set of outcomes. If mesh procedures for SUI and POP are proved safe to continue then the same robust monitoring systems need to be put in place along with non-mesh procedures to ensure outcomes can be compared.

xii. Should specialised centres who can deal with complications only perform the original procedure? If a centre cannot address mesh complications should they actually be performing it in the first place?

6.3.4 STM advocates that the service specifications for the management of mesh should not be finalised until the outcomes of the Review and it must include patient voice.

'*Over 70% of our patients suffer with continence mesh complications, and increasingly we are seeing abdominal mesh suspension complications.*'
Source: Dr Soheil Elneil, expert pelvic mesh removal surgeon, UCLH, quoted June 2018
See Annex 14 Mesh and Surgical Removal by Soheir Elneil

## 6.4 Translabial 3D/4D ultrasound scanning

6.4.1 STM urges the Review to consider the need for translabial 3D/4D ultrasound scans to be included as part of the current suite of diagnostic tools in pre-operative multidisciplinary assessments. This needs to be considered for inclusion in the service specification currently being developed for mesh removal. This is an important issue to address given Lord O'Shaughnessy's response in QWA HL7404.

https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Lords/2018-04-30/HL7404

6.4.2 In the absence of a ban on pelvic mesh devices, there is an urgent need for translabial 3D/4D ultrasound scanning to be used systematically for patients before, immediately after insertion and at timed intervals in the longer term. The purpose of this technique is to contribute to monitoring how the architecture and location of transvaginal mesh changes over time due to polypropylene being unstable in the body and the related damage it causes. Only 3 of the 19 mesh specialist centres have translabial ultrasound scans. Here, trained radiologists have been able to see mesh eroding into women's urethras; eroding into the bladder and vaginal walls; whether mesh is sitting in the wrong position; and whether the architecture of the mesh is twisted and degraded.

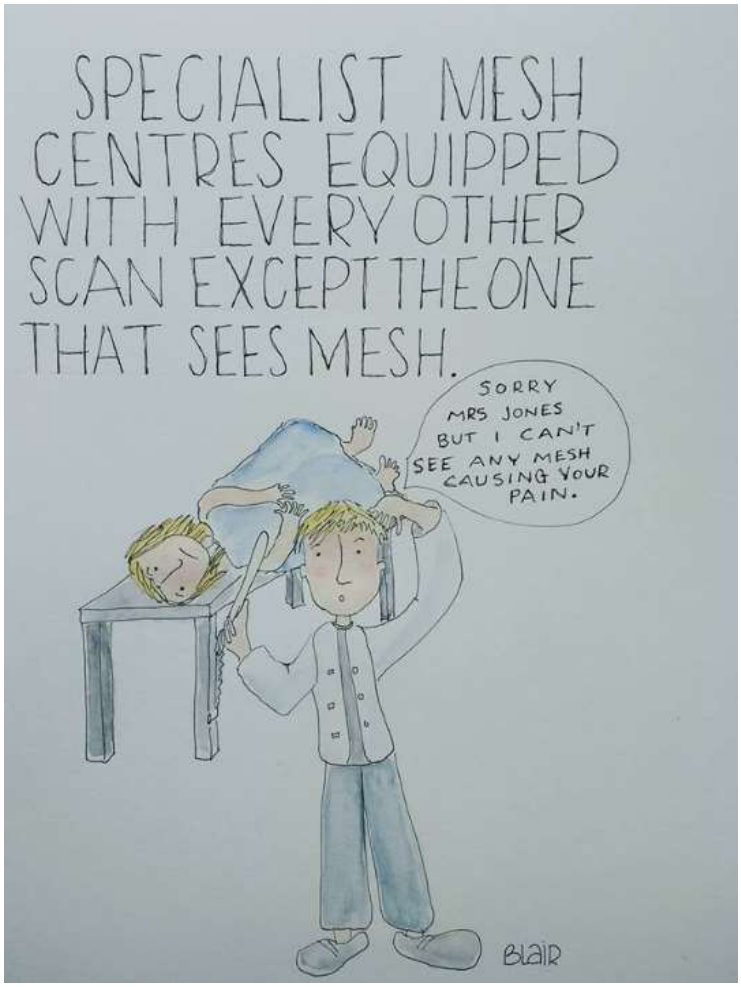
6.4.3 Trained radiologists report that ultrasound scanning is a safe and cost effective technique that does not use irradiation. As well as for patient monitoring purposes, all patient data could be used in a long -term research study to confirm the extent of mesh related complications. Trained radiologists report that imaging modern synthetic implants that consist of wide-weave polypropylene mesh and sling implants are highly echogenic in the anterior vaginal wall on ultrasound but not visible on X-ray, CT or MRI. As a result vaginal and translabial ultrasound have been used to assess slings and meshes for over a decade. STM recommends evidence is sought from the few scanning centres that have experience to obtain clinical opinion from radiologists and surgeons. While in scientific terms this evidence is considered a Grade 4, (the lowest type of evidence according to NICE grading scheme guidelines,) this frontline experience should be taken seriously, along with well-informed patient voice. STM Scotland campaigners requested translabial ultrasound scans 7 years ago but have been ignored.

6.4.4 STM believes the reason translabial ultrasound scans are not routinely used is because hospitals do not have the extra two gadgets to attach onto basic ultrasound scanning machines. Two special transponders are needed (one internal and one external) which are not costly. Radiologists can easily be trained in this. STM is concerned translabial ultrasound scans are not being offered because:

i. RCOG will not accept it is cost effective to train radiologists. Mesh complications are only just starting to be taken seriously by RCOG because of patient voice, so little research has been conducted.

ii. RCOG know many of the removal surgeons who implanted mesh so may not want to find obvious problems on a scan that could be used in medico-legal cases against them or other mesh implanting surgeons.

6.4.5 STM anticipates the Review will recommend that the national specialised commissioning team investigate why translabial ultrasound scans are essential in pre-operative multidisciplinary assessments for inclusion in the service specification and consider the costs and benefits of introducing systematic use of translabial ultrasound scanning as part of the current suite of diagnostics.




## 6.5 Concerns with NICE draft revised guidelines GID-NG10035

6.5.1 STM welcomes the long awaited updated NICE guideline for management of SUI and POP and treatment of mesh complications. However STM is extremely concerned that the draft guidelines GID-NG10035 that replaces CG171 2003, contain very little change from the 2003 version. STM strongly disagrees with the apparent 'business as usual' approach of continuing the use of mesh as a second line option for repair alongside traditional repairs, despite reports of widespread mesh complications. STM's understanding is that no other NICE

guidance exists for a condition where a large portion of the guidance is devoted to dealing with the fallout for one of the treatments, in this case mesh.

6.5.2 STM has a number of general concerns highlighted below concerning the draft CG171 guidelines as follows:

i. There appears to be little change in the updated CG171 regarding mesh use. The updated guidelines allow for mesh use as a second line option alongside traditional repairs. Mesh procedures should be the 3rd line last resort after physiotherapy AND non-mesh surgeries have failed. Otherwise it will be 'business as usual' and another mesh tragedy is inevitable.

ii. The draft revised CG171 guidelines do not provide reassurance that women affected by mesh will receive timely and appropriate treatment. Significantly, the current guidelines suggest that women considering mesh implants continue to be exposed to unacceptable risk and may not be properly informed of risks before choosing mesh surgery.

iii. STM is also concerned about similar complications of pelvic mesh used for rectopexy. In the NICE document on mesh complications management one of the recommended treatments for bowel problems after mesh surgery is another mesh in the form of a ventral mesh rectopexy. It is only mentioned once in the guidance. STM is concerned that if a woman gets complications from one mesh implant, common sense should suggest she is more at risk of complications from a second. STM has heard the stories of women with multiple meshes in a dreadful state.

iv. The draft CG171 guidelines are misleading in stating all procedures have uncertain long-term outcomes. Mesh has an additional layer of complications long term compared to non-mesh. While mesh complications are specified in the draft guidelines, it is essential that the guidelines ensure that surgeons are mandated to provide verbal and written communication to women considering mesh on mesh related risks as part of the informed consent process. The current guidelines are vague about the process of informed consent and do not include a standardised list of risks for surgeons to communicate to patients.

v. There is a U-turn in the draft NICE CG171 guidelines in the use of transvaginal POP mesh. This is shown in the contradiction between the NICE draft guidelines and the IPG599 guidelines. The draft CG171 guidelines recommend that transvaginal POP mesh can now be used if all else fails, while the IPG599 guidelines state that mesh to treat POP should only be used in a research context, effectively banning its use. In the NICE literature review (p.72 in the following link) for the draft CG171 this U-turn is justified by stating that the committee disagrees with the prior NICE review on prolapse mesh for anterior/posterior repair (transvaginal prolapse mesh). It is not clear what scientific evidence precisely NICE has based this U-turn on. Further justification for the U-turn by NICE goes on to state, "The committee agreed that giving women a choice in which procedure she undergoes was very important, and that women should be provided with all the potential benefits and harms regarding each procedure which are relevant to her prolapse was crucial." STM's position is that this statement does not stand up to scrutiny given that long term harms are not known so a woman does not have choice as she does not know what she is signing up for.

https://www.nice.org.uk/guidance/GID-NG10035/documents/evidence-review-4

vi. The NICE guidelines and literature review have omitted key scientific evidence to justify recommendations in the use of mesh to treat POP and SUI. Scientific evidence should be included to justify the recommendations of continued use of TVT. STM questions why TVT is still recommended to be safe to use when, for example, the recent Keltie study demonstrated a complication rate within 5 years of a mesh procedure was 9.8 per cent. This study includes acknowledgement that the true complication rate is likely to be higher. The question the related NICE scientific literature review set itself is what is the most effective surgical management for women with both SUI and prolapse. So going by this table in the Nature paper https://www.nature.com/articles/s41598-017-11821-w/tables/1 STM would like clarification why this data has not been included in the literature review?

vii. STM questions why NICE continues to recommend mesh use when there is no need to use this medical device. Scientific evidence and patient experience has proved that when mesh is used it adds another layer of complications - so why is NICE exposing patients to additional risks? Why commit to letting women go home after a day mesh procedure assuming that mesh is better because recovery is faster compared to traditional repairs, when actually longer term risk of complications are higher for mesh and costs more?

viii. STM is concerned about a potential conflict of interest of NICE guideline authors**.** The clinical lead for NICE guidelines co-authored the Ward Hilton RCT study on the Colposuspension vs TVT for SUI and received funding and materials from mesh manufacturer Ethicon Ltd, a subsidiary of Johnson and Johnson, up to the last study update in 2008. STM is also concerned that the Ward Hilton RCT's outcome measures were limited to effects on SUI and do not include all mesh related complications such as chronic pelvic pain and dyspereunia. STM argues this evidence may influence guideline decisions in favour of continued use of TVT? STM would like clarification on this issue from the NICE person responsible for transparency in the development of these guidelines.

ix. The draft guidelines only mention creating a database for mesh.

a) Surgeons need to record ALL SUI and POP procedures (mesh and non-mesh) to enable the database to have a non mesh-comparator. That way there will be evidence to show risks of mesh and non-mesh i.e. Burch Colposuspension vs. TVT.

b) Recording of long term data by ALL surgeons should be mandatory given there is evidence of a history of underreporting by surgeons. There should be professional and employment consequences for not reporting i.e. employers and/ or professional disciplinary process. Fines should be imposed on hospitals for not ensuring mandatory reporting.

c) Unclear how this database will operate as only a few holders of the database can access all of the data. Partial data is not meaningful and will be a waste of resources.

d) Mesh centres need access to this database to be able to see what is occurring in real time.

e) Mesh centres needs to publish their figures on mesh insertion, complete mesh removals, partial removals and outcomes. A 'core outcome set' needs to be developed to enable a better understanding of which treatments are best and avoid reporting of a selection of outcomes.

f) There needs to be a lifetime follow up of data collection, not just 6 months, given scientific evidence that multiple mesh complications occur years after insertion. Recording data for a mere 6 months post-surgery will not capture all women with mesh complications and the data will not tell the true story of complications.

g) If the above points are not included in the guideline STM questions what are the advantages of this new database?

h) The database has excluded ventral mesh rectopexy.

i) The guidance specifically states the database is only for polypropylene. Yet the guidance also recommends the use of biological mesh for anterior wall prolapse. A database needs to include all types of mesh, as well as non-mesh.

x. The draft guideline is vague on informed consent and specific risks related to mesh sling procedure, except to tell the patient mesh is a permanent implant and difficult to remove. STM does not agree with the term 'discuss' the risks and benefits as this allows room for surgeons to be selective in discussing risks or downplaying risks of mesh. The proportion of women affected by mesh must be defined in numbers with the scientific references. Without this information a surgeon cannot give fully informed consent. Leaving doctors to communicate risks without stating precisiely what these are is likely to lead to history repeating itself i.e. lack of informed consent and a continuation of the mesh tragedy. STM believes the list of standardized mesh complications that occur immediately after mesh insertion or in the longer term should be included as part of the informed consent process, including:

- Dyspareunia
- Partner injury or pain (penile caused by exposure of mesh in vagina))
- Loss of sex life (result of dysperuenia)
- Vaginal bleeding, discharge
- Bladder - recurrent urinary tract infections, incontinence, OAB, retention and voiding difficulties
- Neuromuscular problems – weakness in legs/pelvis, disability (caused by nerve damage/irritation)
- Acute and/or chronic pain in the inner groin, buttocks, lower back, inner thigh, leg, feet, perineum, pelvis, abdomen (caused by nerve damage/ irritation)
- Severe and chronic pelvic pain when sitting down/walking (caused by nerve damage/ irritation)
- Bowel - pain, bleeding, mucus, incontinence, constipation
- Auto immune conditions*
- Fibromyalgia
- Anxiety and depression
- PTSD
- Oedema (legs, feet)
- Swollen abdomen (bloating)
- Paresthesia (itching, pins and needles)
- Skin rashes

- Hair loss

* Lupus, Sjorgren's Syndrome, Psoriasis, thyroid

xi. In addition the draft guidelines does not include requirement for patients and their GP to be given a copy of the serial number of device that was inserted and included with the device kit. This is vital information for patients should they wish to report a device complaint to the MHRA in the future.

xii. STM strongly disagrees with recommendations in the draft guideline for partial removal of mesh in the event of complications. Removing only part of the mesh only removes part of the problem and has been unsuccessful in women with mesh complications. The majority of women go on to have further surgeries after a partial removal, prolonging their suffering and increasing costs to the NHS.

xiii. STM's position is that all patients should be followed up for life given mesh complications occur years after device insertion.

xiv. All vaginal exposures of mesh cause pain and are at risk of infection, regardless of the size of mesh exposed. STM members' experience is that non-surgical treatment with topical oestrogen cream does not fix the problem, but it does prolong their suffering. NICE does not provide specific evidence to justify this treatment. STM strongly argues for any women with a vaginal mesh exposure, regardless of size of mesh exposure, to be referred immediately to a regional MDT for treatment.

xv. STM strongly disagrees with the draft guideline on managing pain and sexual dysfunction. A woman with mesh complications presenting with pain should receive imaging and pain relief and be referred to a regional specialised MDT for further treatment. Many STM members have received strong pain relief medication for years reducing their quality of life further due to severe side effects of drugs. Psychosexual counselling, vaginal oestrogen, dilators and physiotherapy do not work if a woman suffers from pelvic pain and/or dyspareunia. STM's experience is that these treatments prolong the suffering of women and are a significant waste of NHS resources.

# Action 7. Compensation to be paid to all those affected by pelvic mesh in the UK

## 7.1 Lack of warning of risks of significant injuries

7.1.1 Women's lives have been ruined by pelvic mesh and the vast majority were not given fully informed consent about the potential long term, severe and devastating risks. Even after the Montgomery and Thefaut ruling women are not being given full informed consent. This is occurring despite surgeon societies insisting their members are being transparent about risk. Some surgeons have even denied they are using mesh. Some women have been given standard hospital information leaflets about one procedure (e.g. TVT), but then given another (e.g. TOT), which carries different risks, which they have not been able to consider. Women who have been maimed who were not warned of risks of complications should be compensated for their physical losses including bowel and bladder removals; having to use colostomy or urine bags; self-catheterising due to bladder damage; disabled due to nerve damage; chronic pain; dyspareunia and lost sex lives. Emotional trauma, social and economic losses have resulted from these physical losses including breakdown in relationships and marriages; inability to participate in social and family activities; loneliness, lost confidence, isolation, anxiety, severe depression, PTSD; lost homes, significantly lost earnings or lost jobs and state and occupational pension contributions that negatively impact on women and the family income.

## 7.2 Financial costs to mesh injured women

7.2.1 The significant financial costs to mesh injured women associated with multiple visits to health professionals should also be considered. These include costs of multiple trips to GPs and hospitals; lost earnings due to taking time off; job loss or reduced hours through disability and chronic pain; overnight accommodation costs if visiting specialists miles from home; medication; incontinence pads. See Annex 7 for case study indicating costs.

7.2.2 STM strongly believes it is imperative that women, who trusted the surgeons, the NHS, RCOG, MHRA, NICE and the Government to ensure their safety and welfare, receive some redress for their suffering, given that many cannot claim through legal channels due to the reasons described below. These women are unwitting victims and should be compensated accordingly. STM members have been denied PIP benefits as assessors are not aware of mesh injuries including chronic pelvic pain, not being able to sit down for long periods and other disabilities. Yet if a mesh injured woman can walk 200 yards she is excluded from PIP by assessors.

**Box 11: STM Member's Frustration with PIP Application Process**

I've just applied for enhanced PIP. It has taken me until 7 months into recovery from mesh removal and ileostomy to pluck up the energy to do it. I sent forms off 6 weeks ago and hadn't heard anything, so phoned them yesterday. I was told that my file had been sent to ATOS, to arrange a medical etc and I would get an appointment soon. WELL I LOST THE PLOT. I went ballistic and told the lady that I had already nearly had a nervous breakdown when I first claimed it, being turned down and put through the trauma of going to appeal and WINNING! I supplied a letter from (consultant) detailing everything and am categorically not being put through being sat in front of a non medically qualified pen pusher, to decide my fate, or being put through the appeal process. I told lady to catch up on Mesh injuries and butcher surgeons and do a paper assessment, or they would have more suicides on their hands. Brutal but I've had enough. How can an ATOS worker even begin to know what we are suffering. This is not self inflicted, it is a national outrage and it's time DWP were informed about the mesh scandal. Excuse the rant but I'm sure this will touch a nerve with lots of you?

*Source: Comments shared STM Facebook forum, July 2018*

7.2.3 It should also be noted that for those women who do successfully sue for compensation in court, it will take many years for them to be paid, as manufacturers with vast financial resources at their disposal can afford to appeal these cases. Women need money now to pay for medical expenses and to help alleviate some of the hardship which mesh has caused (e.g. lost jobs, reduced incomes, homes, mobility, pension contributions).

# Action 8. Review limitation periods for litigation for medical negligence and product liability for mesh injured women

## 8.1 Delayed onset of pelvic mesh complications

8.1.1 Mesh complications can often take years to occur after insertion. Studies have also shown delayed perforation of bowels, bladders, urethra and vaginal walls. In addition, women who have mesh implanted years before menopause then find that when their vaginal wall thins as a natural part of the ageing process that complications arise. Many pre-menopausal women with mesh devices therefore may be ticking time bombs. Women with delayed onset of symptoms will be out of time for medical negligence and product liability claims. Furthermore, many women were told that they were one of the rare patients who experienced complications and/or their complications were not due to mesh, further delaying their path to seek legal redress.

## 8.2 Barriers to legal compensation

8.2.1 Limitation in mesh cases for medical negligence will not necessarily run from the date of the insertion of the mesh. The claimant may not have had symptoms immediately or may not have had enough information to ascertain that it was the mesh which caused the symptoms and/or physical injury sustained. The date of knowledge will be assessed when the claimant knew:

a. That the injury was significant.
b. That the injury was attributable in whole or in part to the act or omission which is alleged to constitute negligence.
c. The identity of the defendant.

8.2.2 In many cases, unless the Claimant has been informed there has been a defective insertion of the mesh or has realised they have been consented incorrectly, the limitation date may not have triggered until the beginning of the press campaign related to mesh.

8.2.3 There was a change in the law regarding consent in 2015 following the case in Montgomery v Lanarkshire. Anyone who tried to bring a claim prior to that Montgomery ruling may therefore have had the case turned down on consent.

8.2.4 It may also be the case that because less was known about the problems with mesh, consultants who were asked to report on whether there was a breach of the duty of care, may not have addressed this correctly in cases prior to 2017. Sadly it will be difficult to resurrect these files as the claimant will have known there was a probable case at the time of initial instructions.

8.2.5 In addition, there may be a number of women who were informed prior to 2017 that the mesh was inserted incorrectly, who either did not know the limitation periods and due to embarrassment, could not face instructing Solicitors.

8.2.6 In respect of product liability, there is a complex long stop provision, which states that all cases will be out of time ten years after the individual product was manufactured. The mesh may well have been manufactured for some time before it was inserted. As a result, any case where mesh was manufactured before 2008 will now be time barred. For example, in the USA there is no limitation period for product liability claims, which means women in the UK are time barred from seeking compensation from the same manufacturers against whom mesh injured women in the USA have successfully won cases. This anomaly needs addressing.

8.2.7 STM patient experience includes the following difficulties when attempting to sue surgeons or manufacturers:

- Conflicted medical legal experts writing medical reports for an individual case. Apparent conflicts of interest include being pro-mesh, knowing the surgeon who implanted the mesh, or has received payments from mesh manufacturers.
- Paralegals/ trainees handling cases, rather than a fully qualified solicitor. Cases pass through different paralegals as they rotate through departments in their law firm as part of their training. Poor supervision by a qualified solicitor of paralegals/trainees dealing with the case.
- Solicitors not following up inconsistencies/ inaccuracies in medical legal reports or hospital notes when challenged.
- Solicitors taking so long dealing with cases and/or dropping cases so that there is not enough time to engage another solicitor before limitation periods expire.
- Not being advised of product liability as a potential legal remedy.
- Unable to sue the initial law firm for poor handling of the case due to being out of time.
- Being told that complications are rare and consultants are not obliged to know or inform patients about every rare complication that could occur.
- Women finding out years later that their complications are not rare, and the complications were played down by surgeons and/or manufacturers but they are now out of time to sue.
- Incidences of mental health being used as a method of discrediting women during legal action. Women told that since they have experienced mental ill health, (the cause may or may not be due to mesh complications), they will not be a considered a strong or credible plantiff.
- Women wasting years being referred to various specialists because of either denial or ignorance that their complications were caused by mesh. By the time they find a doctor that recognises that their problems are caused by mesh, they can not find a lawyer to take their case or they dropped their case because it was out of time.

8.2.8 Given that complications of pelvic mesh implants often occur years after implant the current time limitations present significant barriers to many women accessing legal

compensation through legal channels. There needs to be an urgent review of these legal barriers to women obtaining justice.

# Action 9. Development of a registry of pelvic mesh implants to track mesh devices and complications and national recall;

## 9.1 Need to capture accurate data for mesh use and mesh complications

9.1.1 Mesh injured patients can make complaints about poor treatment through existing channels to the service provider, NHS Improvement, Parliamentary Health Service Ombusdman, the Care Quality Commission and MHRA. However, there is no one mechanism that exists to report mesh complications directly. The problem to be solved is that rigorous analyses of all mesh patient complications to help identify problems in patient safety is currently impossible. The key then is for a mesh medical device registry to be set up and a national recall conducted as a priority.

9.1.2 A mesh device registry and a national recall will allow assessment of medical device performance in a real-world setting. A national recall and a mesh device registry can contain data on large numbers of patients who have received/are receiving care in diverse clinical settings and include clinical outcomes over time, thus providing a critical platform for capturing the experience with a medical device throughout the device and patient lifecycle. Moreover, by linking device exposures and long-term outcomes, registries permit follow-up that can span decades.

9.1.3 The Mesh Oversight working group's 2017 report confirmed that it is very difficult to ascertain the true rate of adverse incidents for pelvic mesh procedures. The group recommended the establishment of a registry to provide this as well as data on the longer-term outcomes of these procedures. The registry would need to differentiate between products. Due to the financial implications of establishing such a registry, the working group recommended a cost/benefit analysis should be undertaken at the earliest opportunity to inform discussions on whether such a registry would be viable and the scope for using and building on existing data sources. The registries sub group is supposed to consider the best way to capture accurate data on the use of mesh and mesh complications. The sub group was supposed to report on its findings and make recommendations by November 2017. However, there is no information available on progress since there has been no patient representation in any of the working groups since December 2016. STM advocates for establishing a mesh device registry as a priority and for this Review to evaluate the effectiveness of the Mesh Oversight Working Group and review its progress on recommendations and actions taken since the publication of its report in July 2017.

9.1.4 STM advocates that the use of pelvic mesh implants in the UK should continue to be halted, whilst a national audit of the complications and death rate is carried out in the form of a national recall of women who have received these devices since 1997. This is imperative to enable fully informed consent under the Montgomery ruling in which women must be made aware of the true complication rate.

At any point that pelvic mesh is still in use, a national registry for all pelvic mesh implants, urogynaelogical and colorectal, should be in place.. As the following BMJ article states, “A mandatory database is long overdue.”

https://www.bmj.com/content/363/bmj.k4231

9.1.5 STM also advocates a national databse be put in place for hernia mesh that has been used widely for 30 years without any NICE guidelines.

## 9.2 Need for accurate data on rate and causes of death due to mesh complications

9.2.1 Between 2005-2015 the MHRA recorded 13 deaths related to mesh material used for pelvic repairs. The additional recent deaths of two women in 2018 shows mesh complications listed as a contributing factor. STM is concerned there may be other deaths related to mesh, but the underlying cause of mesh is not listed on the death certificate due to lack of knowledge of clinicians or the patient's family or other reasons. A high number of deaths in UK are caused by sepsis due to urogynaecological complications, but it is not known whether or how many patients had mesh implanted. For example, in August 2018, Eileen Baxter died from sepsis and organ failure due to complications of sacrocolpopexy mesh inserted in 2013. The following sacrocolpopexy study accepts mesh risk is 10 per cent.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3025104/

NICE accepts there are serious but well recognised safety concerns. These safety issues should be communicated to patients, but patient experience tells us this is not the case.

https://www.nice.org.uk/guidance/IPG583/chapter/1-Recommendations

https://www.scotsman.com/news/uk/grieving-son-who-lost-mother-to-mesh-set-to-meet-health-secretary-1-4801952

9.2.2 In January Lucinda Methuen Campbell committed suicide by hanging after she could no longer endure the chronic pain and related psychological suffering caused from a rectopecxy mesh implant and her ovaries being removed without her consent at the same time.

https://www.telegraph.co.uk/news/2018/05/29/woman-killed-surgeon-removed-ovaries-operation-getting-way-inquest/

In both cases, women were not suffering from a life threatening condition. Their mesh implants caused new onset of chronic pain that was far worse than the original condition. In the case of Eileen Baxter mesh complications contributed to her death and in the case of Lucinda it was a contributing factor for her suicide. The establishment of a registry and retrospective audit may provide a more accurate figure of deaths due to mesh complications.

# Action 10. Consider the effects of commercial influence on the published research on mesh and consider the introduction of an American style Physicians Sunshine Payment Act to ensure mandatory reporting of all payments from industry to clinicians involved in research

## 10.1 Management of conflicts of interest needs to be improved

10.1.1 STM believes the Review team should issue a strong recommendation to the Government to introduce a Sunshine Payment Act for the UK as a matter of urgency. STM called for a Sunshine Payment Act during a debate in the Houses of Parliament in April 2018 as recorded in Hansard.

https://hansard.parliament.uk/Commons/2018-04-19/debates/C5B94EB2-2398-4F0E-BE9E-D502ACEBFA62/SurgicalMesh

10.1.2 Given the controversy over the financial links between drug and medical device companies and consultants, professional and patient bodies, and journals, it is clear that the management of conflicts of interest needs to be improved. STM believes a Sunshine Payment Act is needed to enable all payments from industry to medics and teaching hospitals can easily be searched by the public.

10.1.3 The Sunshine Payment Act was passed in America in 2013. The aim is to make it easy for everybody to search an online database to see what funding has been made from industry. Following the Act, a 2014 article in Health affairs noted that:

"Financial relationships between physicians and medical product manufacturers are common and can include everything from free meals to consulting or speaker fees to direct research funding. These relationships can have many positive outcomes and--particularly in the context of consulting and research funding--are often a key component in the development of new drugs and devices. However, they can also create conflicts of interest and in some cases can blur the line between promotional activities and the conduct of medical research, training, and practice"

https://www.healthaffairs.org/do/10.1377/hpb20141002.272302/full/

10.1.4 Fiona Godlee, editor of the British Medical Journal, said in a BMJ article: "We don't let judges or journalists take money from the people they are judging or reporting on: we shouldn't let doctors do this either. Paid opinion leaders are a blot on medicine's integrity, and we should make them a thing of the past."

https://www.bmj.com/content/363/bmj.k4157

10.1.5 STM would like to see an American style Physician Payments Sunshine Act to ensure that all payments from industry to medical professionals and teaching hospitals are transparent. That way anybody reading trial paperwork can instantly check to see if the authors have financial ties to industry and therefore be at risk of bias. In the United States it is the responsibility of the companies to declare payments to the Centers for Medicare & Medicaid Services (CMS). It is easy and free for the public to navigate https://openpaymentsdata.cms.gov/

STM's position is this financial transparency is urgently needed in the UK so that we can shine a spotlight on conflicts of interest. At the moment there is only a voluntary reporting database, which was set up in 2016 by the Association of the British Pharmaceutical Industry (ABPI). Disclosure of payments to this database is not mandatory and it only covers drugs and not devices.

10.1.6 STM is aware that funding from industry to a doctor, a research hospital or a medical study does not automatically mean there is a risk of bias. However, there are numerous studies, which show that research, trials and papers sponsored by industry are more likely to find results that are biased toward the product or procedure they are writing about.

For example:

• Lexchin et al says: "Systematic bias favours products which are made by the company funding the research. Explanations include the selection of an inappropriate comparator to the product being investigated and publication bias." https://www.bmj.com/content/326/7400/1167

• Lundh et al concludes that "Drug and device studies sponsored by manufacturing companies have more favourable efficacy results and conclusions than studies sponsored by other sources."

https://link.springer.com/article/10.1007/s00134-018-5293-7

In Denmark, France, Slovakia, and Turkey there is legislation in place to mandate financial disclosure. This is desperately needed now in the UK.

10.1.7 Professional bodies should provide advice to their members about the levels of industry sponsored hospitality and payments that are acceptable. This advice should be included in the Codes of Conduct of NHS employers and Professional bodies.

# Action 11. The case for a full Public Inquiry or Royal Commission

## 11.1 The need to address a history of failures and implement reform

11.1.1 This submission has highlighted the failings of the regulatory and legal system in both protecting those affected by pelvic mesh and the barriers to access justice and adequate healthcare pathways. The regulatory failings, the access to appropriate healthcare and justice are typical of the way in which mesh patients in the UK have become disenfranchised by the current regulatory and legal systems. In determining this Review, Baroness Cumberlege now has a unique opportunity to give those affected by pelvic mesh a proper hearing of their concerns. Those concerns relate both specifically to pelvic mesh devices and the regulatory, legal and healthcare failings exposed by the history of mesh devices.

11.1.2 STM believes a public inquiry or Royal Commission is justified due to the large scale of serious health and safety issues and failure in regulation. In our submission, the experience of mesh in the UK constitutes a significant widespread harm that could have been avoided but for the inadequate and delayed regulatory response of the UK Government and the responsible manufacturers and lack of informed consent. It is noteworthy that the State of California started proceedings against Johnson and Johnson and Ethicon on behalf of its citizens; vaginal Case 7-2016-00017229-CU-MC-CTL - The People of the State of California v Johnson & Johnson, Ethicon. It is also worth noting within this document it states that Johnson & Johnson played down and misled consultants about the frequency of mesh complications.

https://www.classaction.org/blog/johnson--johnson-destroyed-transvaginal-mesh-documents-court-rules

The States of Washington and Kentucky have also started proceedings against Johnson and Johnson on behalf of its citizens.

https://www.bmj.com/content/353/bmj.i3045

https://www.statnews.com/pharmalot/2016/08/16/johnson-and-johnson-vaginal-mesh-lawsuit/

https://www.cbsnews.com/news/states-file-lawsuit-against-johnson-johnson-over-pelvic-mesh-implants/

11.1.3 STM believes an Inquiry into the long term regulatory and legal systemic failures to

investigate the cause of mesh injuries offers an opportunity of a reformed approach to the way in which medical products are regulated; this may be a significant opportunity as UK exits the EU and its wider regulatory context.

11.1.4 A public inquiry will also provide an opportunity to examine the structure of UK's licensing of medical products in order to determine why it is that funding the 'externalised' cost of adverse consequences to users of these products falls always upon national and local Government, rather than upon the profit generating manufacturer. The obligations we have in mind are the costs of:

- supporting mesh injured women through NHS and local authority social care
- supporting mesh injured women through payments of benefits
- support for mesh injured women who are unable to return to paid work.
- litigation pursued against NHS practitioners in the stead of Manufacturers who for systemic and funding reasons are often too expensive and/or too difficult to sue.

## 11.2 Need for a medical device manufacturers levy scheme for those harmed by products

11.2.1 STM concurs with the Valproate submission that,

> 'in large product liability group actions in future, consideration should be given to whether or not a Government body should be a party to litigation against medical products manufacturers specifically to seek recovery of these costs. Alternatively, whether as a condition precedent of product licencing, manufacturers should provide financial guarantees (or at least suitable commercial indemnity insurance based on numbers of patients prescribed their drug or using their medical product) to cover such contingent costs. For example, in Nordic countries a Manufacturer Levy scheme is used to resource a centralised Medical Devices and Pharmaceutical Injuries Compensation Scheme for the benefit of all those injured by products cleared for sale in Nordic markets, at the expense of all Manufacturers who access these markets.'

STM also suggests a tax placed on profits of mesh medical device products at a rate that relates to the severity and frequency of adverse reactions.

11.2.2 In addition, STM believes a public inquiry or Royal Commission will enable consideration of the impact of the findings in mesh cases in the USA have had upon delaying the recognition of the harm done by mesh to women; preventing continuing harm; enabling information about risk to come to the attention of regulators. For example cases in which the behaviour by manufacturers Johnson & Johnson (J&J), Ethicon has been raised: -

- J&J employee "Dr. Axel Arnaud, believed POP devices to pose such risks to sexual function that he suggested including a warning specifically aimed towards sexually active women. In a June 2005 email, he proposed adding the following warning:

WARNING: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggest the risk of such a complication is increased in case of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman." However, J&J never incorporated this warning into any of its marketing or promotional materials.

 J&J's marketing and promotional materials for its mesh devices misrepresented product safety by concealing known risks and complications. J&J also omitted information on risks in its informational, educational, and training materials directed to doctors.

 J&J's high-level employees urged the company to include warnings about known dangers. For example, Dr. Meng Chen, a medical director in the complaint review department, was so concerned with the patients complaints she was seeing related to post-operative pain and dyspareunia, that she requested that the company share this risk. Dr. Chen's concerns included the "type and intensity of the post-operative complications disproportionate to pre-operative consent-expectations." J&J, however, continued to conceal the material risks of dyspareunia and pain affecting quality of life in its marketing and promotional materials.

 J&J destroyed ten of thousands of documents related to mesh lawsuits.

https://oag.ca.gov/system/files/attachments/press_releases/J%26J%20Complaint_1.pdf

Johnson & Johnson Destroyed Transvaginal Mesh Documents, Court Rules

In 2007, "the pharmaceutical giant Johnson & Johnson tried to stop French health authorities publishing a report warning against the use of its untested pelvic mesh devices, two years after they began giving them to Australian women, a court has heard. " (Australian class action reported in link below)

https://www.theguardian.com/australia-news/2017/jul/10/johnson-johnson-tried-to-prevent-report-about-pelvic-mesh-devices-court-hears

11.2.3 When considering whether a Royal Commission is necessary, in addition to the arguments stated above in section 9, a Royal Commission has greater investigative powers to obtain evidence (on or off line) and call witnesses under oath. Those that give evidence are also protected in law against being sued for defamation. It also provides protection for witnesses such as (former) employees of J&J, clinicians, NHS employees, who will be more candid when giving evidence.

## Action 12. Transparency of this Review

12.1 STM strongly believes that in the interests of transparency there is a need for this Review to be independent of any medical professional who is involved in the implanting or explanting of pelvic mesh devices. Also any medical professional who has previously received payment of any kind from a pelvic mesh manufacturer should not take part in this Review. A surgeon member of the APPG, Vincent Argent, has expressed concern that GPs and O&G colleagues are not aware of the Review and assumes the Review will generally publicise the evidence gathering public meetings.

# Conclusion

In STM's view the professional bodies responsible for safety of medical devices, provision of adequate guidelines for safe clinical practice and effective implementation have failed women miserably through being ineffective in their roles, causing women unnecessary harm and suffering. STM believes the mesh manufacturers vigorously marketed their products resulting in widespread use, the regulators assisted them on the weakest evidence, and the medical profession, which failed to ensure surgeons were adequately trained or that patients were informed of the risks. Most importantly, there was a monumental failure to establish comprehensive registries for all mesh procedures that might have identified unforeseen complications far sooner. For these reasons STM's position is that mesh devices should be permanently banned.

The use of pelvic mesh devices continues to be promoted as being anatomically effective in treating women, but the lack of good quality evidence based research shows the medical profession simply do not know whether it is effective for 'many' women in the longer term. While evidence-based medicine is a noble ideal, marketing-based medicine is the current reality. The lack of robust evidence based research, postmarketing studies, weak management of financial conflicts of interest, national registry for mesh devices, monitoring and evaluation of outcomes, and appropriate regulation has been ignored for 21 years and is urgently needed for all mesh medical devices.

The science of polypropylene has been ignored; multiple scientific studies show that polypropylene is not biocompatible in the human body as it degrades and erodes over time causing severe complications. The research showing various degrees of degradation of polypropylene devices, including depolymerization, cross-linking, oxidative degradation by free radicals, additive leaching, hydrolysis, stress cracking and mesh shrinkage along with infection and chronic inflammation has been ignored. These alterations in the chemical structure of polypropylene result in the loss of structural integrity through the material becoming brittle and therefore it is not safe for use in the human body. The paucity of long term data on outcomes in the research literature; the focus of short term flawed or biased science research on rates of improvement for incontinence, bowel symptoms and pelvic organ prolapse at the expense of safety; and vast gaps in data collection from multiple monitoring systems, has led to life changing injuries to women being ignored for far too long.

Complications occurring immediately, and many years after implant such as exposure of the eroded mesh into other organs including the bladder, rectum and vaginal wall have resulted in a negative impact on women's quality of life – emotionally, socially, physically and economically. Mesh complications have caused disability due to nerve damage or irritation that results in chronic pain; loss of, or damage to organs has led to self-catheterising and use of stoma bags; anxiety and depression; de nova dyspareunia and inability to have sex. These disabilities have in turn led to women losing partners and marriages, homes and jobs. Thousands of families have therefore been negatively affected by complications of pelvic mesh.

STM believes that individual patients and campaign groups have been treated disgracefully by being misinformed about risks, demeaned and ignored when they have raised concerns over the past 21 years with GPs, surgeons, the NHS, their own MPs, Government and GMC in a culture of denial. While not all doctors are conflicted or ignorant and have treated women appropriately, STM's experience is that there are too many clinicians who are guilty of misinforming and mistreating their patients over many years.

Failure to consider the recommendations in each of the 12 STM Actions in this Review will, in STM's view, render the Review incomplete and will not stand up to scrutiny. It will be seen as a pointless waste of public resources. If the actions points in this submission are not addressed another mesh tragedy is likely inevitable.

STM therefore urges the Review team to consider the following recommendations in the Review.

# Recommendations

## 1. A full ban in the use of pelvic mesh devices following the Review.

1.1 The Review team to consider whether pelvic mesh should be permanently withdrawn from use, in light of all the evidence available to it relating to the safety of mesh.

1.2 Ensure the final NICE guidelines currently being revised for treatment of women for SUI and POP and women with pelvic mesh complications incorporate the findings of this Review. If mesh is not banned the guidelines should only allow for mesh to be offered as a last option for all pelvic procedures once conservative treatments and non mesh surgeries have failed.

1.3 Ensure NHS England service specifications currently being developed for the management of mesh complications incorporate the findings of this Review.

## 2. Visit the science: unbiased review of the science of mesh use in the pelvis and the properties and safety of polypropylene material in the human body over time

2.1 Conduct an independent analysis of the reliability of the prior published literature on pelvic mesh. Assess gaps in the existence of long-term studies (up to 10 years post implant surgery); whether any have been conducted (e.g. as recommended by the HTA appraisal of Gynecare TVT and NICE final appraisal of 2003) to assess long-term complications. Asses concerns about omissions in research protocols (particularly informed consent and QOL questionnaires that focus on SUI with mesh risks downplayed or omitted) for past, current and future pelvic mesh trials in the UK and a suspension of all current and planned trials for any type of pelvic mesh until the outcome of the Review.

2.2 Conduct an independent assessment into whether polypropylene mesh is ill-suited for use in medical implants for two main reasons. Firstly, that polypropylene causes chronic inflammation, chronic pain and erosion years after implant over time. Secondly, review evidence that polypropylene is one of the most unstable commercial plastics on the market. The independent assessment should include within its scope points 2.3 – 2.9 below.

2.3 Conduct an unbiased review of approximately over 400 articles on polypropylene mesh and the body's response to the mesh to obtain the truth.

2.4 Review evidence that polypropylene is so sensitive to oxygen that stabiliser is added immediately it is produced at the factory to prevent instant attack by oxygen. Polypropylene gives the illusion of stability as long as there is enough stabiliser left to protect it. Once the stabiliser is used up protecting the polypropylene, or washed out by contact with water in human tissue, the polypropylene will start to degrade rapidly in the human body. These are well-established facts published in countless peer reviewed journal articles that must be considered by the Review.

2.5 Review evidence that polypropylene is known to cause an ongoing inflammatory reaction because it is not biocompatible in the human body. Truly biocompatible materials are known and they cause no such reaction. Improperly stabilized polypropylene will degrade, lose its strength and eventually break apart. World class experts have confirmed polypropylene mesh is dramatically under-stabilized for its intended use.

2.6 Assess whether any robust research comparing uncoloured polypropylene mesh fibre to blue fibres and its implications for safety of mesh implants have been carried out. Review the evidence that pigments and dyes can make polymers more unstable. It has been shown that the Phthalocyanine Blue Pigment makes polypropylene stiffer and more brittle.

2.7 Review the need for research as follows to examine:

- Biocompatibility of mesh in the body. The role of polypropylene degradation over time in the development of complications of chronic pain.
- Giant cell inflammatory reaction and effects of ongoing inflammatory reaction with a focused examination of explanted mesh material samples.
- The extent and cause of the problem of women inserted with mesh for all pelvic conditions who develop severe levels of chronic pain (including clinical practice and mesh material factors).
- The link between mesh and the development of autoimmune disease and fibromyalgia.

- To what extent mesh-injured women with repeated bladder, bowel and kidney infections are at risk of antibiotic resistance, potential renal failure and sepsis.
- The failure of informed consent and its effects on patient choice and autonomy concerning treatment for pelvic conditions treated with mesh.

The protocols of any future research should include:

- A minimum set of core outcomes that includes all mesh complications, including dyspareunia and chronic pain.

- The time-frame for RCTs should be at least 5 years, preferably 10 years to capture the onset of complications years after mesh insertion.
- Ensure surgeons have the requisite knowledge, surgical skills, and experience in pelvic reconstructive surgery through accreditation.
- Revised Quality of life questionnaires to capture any new onset of pain, infection, dyspareunia. Currently research focuses on efficacy (fixing SUI) and does not properly address additional complications caused by mesh implants.
- Robust informed consent process including all risks.

2.8 Review if and when the relevant bodies in UK (NICE, MHRA, Department of Health, RCOG, BAUS, BCUG, RCS and advisory committees (including the limitations of SERNIP after its establishment) were made aware of the safety issues of polypropylene pelvic mesh devices from 1997 until the present including:

a. Assess if and when the responsible bodies became aware of related research in the science of plastic polypropylene when deciding whether it is appropriate to use polypropylene pelvic mesh implants in the human body and why they have considered it is safe to continue using it over the past 20 years.

b. Assess if and when the relevant bodies in the UK became aware of evidence that polypropylene pelvic mesh is oxidatively unstable in the body and degrades causing erosion and related significant complications;

c. Assess what action should they have taken and what are the implications for safety going forward?

d. Assess if and when the relevant bodies in the UK should reasonably have known about the evidence, given their critical roles and responsibilities in ensuring the safety of patients.

2.9 Undertake a rapid assessment with leading mesh removal surgeons in designated hospital mesh removal centres and other expert mesh removal surgeons to:

a. Evaluate whether and how many vaginal polypropylene mesh implants removed from patients are substantially altered in their architecture; shrunk in width; evidence that polypropylene mesh has folded, contracted, embedded in scar tissue and surrounding organs and the effects.
b. Assess the type and extent of damage caused by the changing architecture of vaginal polypropylene mesh e.g. caused a stricture or worse to the urethra due to the changing architecture of mesh; damage to major nerves, blood vessels, vagina and surrounding organs; chronic inflammation and large foreign body response; chronic pain; effects (including timeframe from insertion of device to onset of symptoms); and outcomes.
c. Assess whether histology tests are being systematically carried out on all removed mesh/tissue complexes, data compiled, analysed and when results will be published. For example some removal surgeons in pelvic mesh centres are known to be conducting histology tests on excised mesh and have

confirmed giant cell response present with nerve and blood vessel entanglement in the mesh-tissue complex. A national research project utilising data from excised mesh/tissue complexes initiated to assess the effects and outcomes using a core outcome set for comparison of results. This will help determine risk factors – whether patients with pain have higher giant cell response; mesh in incorrect position; patient factors e.g. diabetes; mesh material. All factors should be routinely measured.

2.10 Ensure the above points are addressed in the development of NHS England service specifications and revised NICE guidelines currently being drafted.

**3: Review the structures and processes of mesh medical device regulation, approval and adverse affects reporting to enhance transparency and safety**

3.1 In the absence of a ban on the use of pelvic mesh, a patient registry be established for all vaginal mesh implantable devices to enable long term follow-up and surveillance. Such registries should include unique device identification so that any shortcomings can be more readily tracked, patterns of use monitored, and patients later judged to be at risk more easily identified.

3.2 Establish a publicly accessible registry of all mesh devices with details of marketing status and linked evidence to the product.

3.3 MHRA must check that research is designed to provide objective evidence of the efficacy and safety of the pelvic mesh device at the time of licensing.

3.4 Clinical trials lasting at least 5 years with minimum cohorts to be made mandatory in order for any implantable device to be marketed.

3.5 The system of patient reporting to the Yellow Card Scheme be made more user friendly for the public and clinical staff; and more information made accessible for the public to greatly increase awareness of the scheme's existence and purpose;

3.6 Review steps being taken to improve rates of healthcare professional reporting of adverse events;

3.7 Review with NICE the Health Technology Assessment Vol.7 No.21 recommendations for vaginal mesh (see para 3.5) and further actions needed in light of the mesh scandal.

3.8 Review current MHRA progress of actions outlined in its 2014 report relating to recommendations of Stephenson's independent review into the MHRA. Specifically, whether actions have translated into positive outcomes and to identify ongoing constraints.

3.9 Assess what systems need to be put in place to ensure that improperly tested products used in other countries are not used again in the UK as mesh has been.

3.10 Ensure the MHRA and other relevant agencies develop adequate systems and processes as UK moves towards implementation of the new EU Medical Device regulation 745. Assess the implications concerning Brexit.

3.11 Assess what progress MHRA and NHS England has made in improving reporting through MDSO posts and how effective have they been in addressing lack of reporting e.g. for pelvic mesh device adverse events, including reporting the type of device or manufacturer of the product so products can be monitored.

3.12 Safety statements for all mesh devices used by NHS are obtained from manufacturers. Mesh device use to be suspended, until such time as these safety statements are obtained. Safety statements should be required across NHS and private practice.

3.13 MHRA to provide a patient guide on risks for mesh procedures similar to that provided for Valproate.

**4: An overhaul of the HES reporting system to ensure ALL mesh complications are recorded for a patient's lifetime; and to retrospectively correct the vast underreporting of pelvic mesh complications to date through a national recall**

4.1 Recommend a national recall to include women who have had a pelvic mesh device implanted over the past 21 years. This should encompass all including and ventral rectopexy mesh, especially given specific HES reporting codes are lacking or do not exist for this type of surgery**.**

4.2 Assess progress with all of the NHS Mesh Working Group recommendations and timeframes, particularly to address the vast underreporting and gaping holes in HES data collection. Consult the All Party Parliamentary Group (APPG) on Surgical Mesh on actions needed.

4.3 Consult the APPG on Surgical Mesh about the NHS Digital Audit report on vaginal mesh published in April 2018; and with CMO on the responses by stakeholders (including STM) to fundamental mistakes and gaps in the report; consult MHRA, CMO and APPG on the lack of meaningful response of MHRA to the audit report.

4.4 Consider the withdrawal of the NHS Digital audit report until apparent mistakes and gaps are addressed to enable correct and meaningful data to be included once recommendations have been received by the CMO and APPG.

**5: Review the governance, accountability and effectiveness of the medical profession, including relevant institutions responsible for regulation, monitoring and evaluation of the safety of mesh implants in the NHS and private sector**

5.1 Recommend an independent review of MHRA's governance, resourcing and failings in response to the pelvic mesh scandal over the past 21 years.

5.2 Assess BSUG and RCOG failings in response to the pelvic mesh scandal over the past 21 years.

5.3 Review the scale of lack of informed consent for pelvic mesh in the past 21 years and to ensure fully informed consent of all mesh risks, including dyspareunia, is adhered to in practice as a matter of urgency. This includes ensuring standardisation of guidelines including all risks and process; statistically accurate information identifying the potential risk in the use of these products is adopted; only then can true informed consent be obtained from the patient. NHS England, NICE, RCOG, BSUG and BAUS to identify what resources women, clinicians, and health services need to comply with the Montgomery ruling for informed consent relating to mesh. Training and educational materials must be fit for purpose. Consultants inserting and removing mesh urgently need guidance.

5.4 Ensure NHS information leaflets to various stakeholders do not contain misinformation.

5.5 Ensure manufacturers marketing leaflets do not include misinformation and include all risks, including erosion into other organs leading to disability and dyspareunia.

5.6 Define with NICE, RCOG and the APPG what is an 'appropriately selected patient' for polypropylene mesh implants given that polypropylene eventually changes architecture in the body and causes severe complications, even years after implant.

5.7 Recommend urgent actions to address institutional denial of mesh injured women in chronic pain that is still occurring, despite revised information on mesh complications being made available to GPs and consultants. Address real concerns of doctors' poor attitudes to women's health care.

5.8 Review why the relevant bodies did not implement recommendations in the NICE 2003 final appraisal and the Health Technology Appraisal of tension free vaginal tape, 2003, that included further research to include unbiased assessments of longer term performance from follow-up of controlled trials or population-based registries; more data from methodologically sound RCTs using standard outcome measures; a surveillance system to detect longer term complications, if any, associated with the use of mesh; and rigorous evaluation before extending the use of TVT to women who are currently managed non-surgically.

5.9 Review flawed short term trials and assess the urgent need for unbiased long-term trials up to 10 years on the safety of pelvic mesh tape to treat SUI. Standardised fully informed consent and process of all risks must be included and patients given speedy access to mesh removal experts should complications occur. STM believes that its 6,900 members offer a significant resource to retrospectively assess mesh complications, without the need to implant more women with a mesh that is designed to be permanent and whose full removal does not guarantee the damage will be reversed.

5.10 Assess whether it is safe to continue current mesh research (e.g. SIMS, VUE, PROSPECT) or to start new trials, in view of the contents of this submission.

If mesh trials continue: -

a. An experienced mesh removal surgeon should be available as soon as complications occur, as mesh is designed to be a permanent implant.
b. All patients in current and future pelvic mesh trials should be made aware that the mesh was suspended during the Review period; that complications should be reported to the MHRA as well as to trial administrators;
c. Ensure that all participants are given QoL questionnaires that are adequate to capture the onset of all mesh complications.
d. Ensure a Clinical Audit is undertaken of all ongoing trials, to assess complications and whether the trials should be terminated.
e. Contact the Ethics Committee for the SIMS, Vue and PROSPECT trials to ask why the trial results and interim 2-year results have not yet been published and to assess what complications are being captured.

5.11 NHS to urgently provide a full cost benefit analysis to prove to the public that pelvic mesh devices are a cost effective treatment option in the long term. This is particularly important given the multiple complications for which women need treatment years after device insertion.

5.12 Undertake an independent assessment into STM's concerns about omissions in research protocols for past, current and future pelvic mesh trials in the UK and a suspension of all current and planned trials for any type of pelvic mesh until the outcome of the Review.

5.13 Ensure MHRA will comply with the new European Medical Device regulation.

5.14 Replace the Yellow Card system with a 'Maude' type database system (for example as used in the USA), so that reports regarding complications and adverse events on medical devices are open to public scrutiny.

5.15 Address the issues of dyspareunia as follows:

a) Dyspareunia is a common risk and needs to be properly addressed in the NHS England patient information leaflet and the ongoing revision of NICE guidelines CG171.
b) Remove the NHS leaflet known as V12 offline immediately as this leaflet contains misinformation.
c) Inclusion of data codes for incidence and outcomes of treatment for dyspareunia caused by a) mesh erosion/protrusion through the vaginal wall, b) scar tissue, and c) types of chronic pain in the HES episode statistics and other reporting systems by professional bodies such as BAUS and BSUG.

d) Dyspareunia is a risk and common complication that must be included in long term studies on the effects of pelvic mesh devices, and especially in the consent process for trial participants.
e) The pre-operative consent information and process to include the risk of dyspareunia and loss of sex life.

**6. Improved processes to enable mesh-affected women to access fast-tracked quality assured multi-disciplinary services for full mesh removal surgery**

6.1 Ensure better resourcing of multidisciplinary expert health care in specialised mesh centres as a priority for mesh-injured women as follows:

a. Ensure translabial 3D/4D ultrasound scanners and trained radiologists available at all designated specialist mesh removal centres as part of the current suite of diagnostic tests;
b. Ensure GPs are trained to recognise mesh complications and appropriately refer patients to specialists, including addressing paternalistic attitudes towards women patients;
c. Defined pathways of care in training and resourcing for women's health/pelvic floor physiotherapy and specialised pelvic pain management that meets NHS specifications to provide specialist assessment and management of chronic pain for mesh injured women; adequate psychologist/psychiatrist support to help traumatised women and their partners and families; psycho sexual counselling;
d. Defined training programmes for surgeons for full mesh removal as part of the training to be a specialist in female urology or urogynaecoloy or colorectal and reconstruction. Also, training programmes need to specify which mesh: TVT, TOT, vaginal prolapse, abdominal mesh for vaginal prolapse, abdominal mesh for colorectal prolapse;
e. Ensure adequate supply of surgeons that are adequately trained in traditional methods of repairing SUI and POP that do not use mesh devices.
f. Ensure defined resources and training pathways in native tissue repairs and other alternatives to using mesh. Sling the Mesh believes that funding needs to be made available for training surgeons so they can competently perform the following surgery: -

- Burch Colposuspension
- Native tissue slings
- Bulkamid injections
- Kelly Plication
- Prolapse over-stitching
- Delormes
- Suture rectopexy or resection rectopexy
- Sacrospinous fixation for vaginal vault or uterine prolapse

Other alternatives to mesh surgery include pessaries and rings and pelvic floor physiotherapy. Adequate funding needs to be made available for training more pelvic floor physiotherapists, and urology and colorectal nurse specialists, of which there is a national shortage.

g. Adequate pelvic floor physiotherapy programme after birth offered for all women to prevent the need for invasive surgery. A 6-week post natal check-up should be provided by a pelvic floor specialist (with additional training) in addition to a GP check up, which is the current NHS model of service. Ideally pelvic floor exercises should be taught to girls in schools, especially those who take part in high impact sports such as gymnastics and athletics, so they understand how to develop and maintain a strong pelvic floor before they become pregnant.
h. Ensure enough surgeons are qualified to undertake full mesh removals competently Mesh removal is a highly specialised and complex procedure and should only be performed in approved centres as part of the MDT with clear governance and audit. There should be accurate recording of surgical factors, patient factors and mesh material factors; a standard proforma should be developed to collect all this data by type and manufacturer of implant i.e. TVT, TOT, vaginal prolapse, abdominal mesh for vaginal prolapse, abdominal mesh for colorectal prolapse and record of serial numbers kept. All information should be provided to the patient.
i. Defined pathways of care in mesh removal with life-long long-term care and follow up; such as pain management, urinary, bowel and sexual function.
j. Ensure robust data management, audit and governance
k. Ensure all consultants are held accountable to report issues with devices to the MHRA
l. Assess the evidence of NHS England and NICE to justify partial mesh removals as a pathway of care.
m. If NHS England is adamant that 'simple localized excision' is an appropriate pathway for some women presenting with chronic pain, ensure robust fully informed consent process in place including both verbally and in writing of all risks.
n. Assess whether specialised centres who address mesh complications only perform the original procedure.

6.3.4 Ensure NHS England service specifications for the management of mesh be finalised after the outcomes of the Review.

## 7. Compensation to be paid to all those affected by pelvic mesh in the UK

7.1 Ensure mesh injured women can access PIP and ESA benefits; benefit and medical assessors (including DWP and contracted out staff) to be trained in physical and mental health impact of mesh injury on inability to work and function outside of work.

7.2 Establish a process by which all mesh injured women can apply for compensation from the government. Should women obtain financial remedy through the courts, their government compensation could be deducted from legal payouts if these are received.

## 8: Review limitation periods for litigation for medical negligence and product liability claims for mesh injured women

8.1 Initiate an urgent review of the legal barriers to women obtaining justice.

8.2 In the UK there is a limitation period for product liability claims, meaning women in the UK are time barred from seeking compensation from the same manufacturers whom mesh injured women in the USA have successfully obtained compensation. This anomaly should be addressed in the review of legal barriers.

### 9: Development of a registry of pelvic mesh implants to track mesh devices and complications and conduct a national recall

9.1 The establishment of an adequately resourced national registry as a priority to protect patients, improve outcomes, identify best practice and reduce costs.

9.2 Legislation to mandate what must be measured in all patients with mesh implants, since voluntary entry of data has failed miserably, and to ensure reporting requirements are adhered to and complete information is maintained.

9.3 A national recall to be conducted as a priority of all women who have received pelvic mesh devices. If following the mesh suspension the NHS and surgeons insist on keeping mesh for complex cases then it is imperative that a retrospective audit is carried out of ALL women who had pelvic mesh inserted since 1997. Going forward any woman exposed to mesh implant risk must be aware of the true complication rate, for fully informed consent under the Montgomery and Thefaut ruling.

9.4 Evaluate the effectiveness of the Mesh Oversight Working Group and review progress by the Registries sub group on recommendations and actions taken since the publication of its report in July 2017.

### 10: Consider the effects of commercial influence on the published research on mesh and consider the introduction of an American style Physicians Sunshine Payment Act to ensure mandatory reporting of all payments from industry to clinicians involved in research

10.1 Improve the management of conflicts of interest. Given the controversy over the financial links between drugs and medical device companies and consultants, professional and patient bodies, and journals, it is clear that the management of conflicts of interest needs to be improved to limit potential for bias.

10.2 Issue a strong recommendation for legislation mandating the declaration of payments to healthcare professionals by drug and medical device companies. An American style Physicians Sunshine Payment Act to be considered in UK to ensure mandatory reporting of all payments from industry to clinicians involved in research..

### 11: Consider the need for a full public inquiry or Royal Commission

11.1 Initiate a public inquiry or Royal Commission to provide an opportunity to examine the

structure of UK's licensing of medical products in order to determine why it is that funding the 'externalised' cost of adverse consequences to users of these products falls always upon national and local Government, rather than upon the profit generating manufacturer. The obligations STM has in mind are the costs of:

- support for mesh injured women through NHS and local authority social care
- support for mesh injured women through payments of benefits
- support for mesh injured women who are unable to return to paid work
- litigation pursued against NHS practitioners in the stead of Manufacturers who for systemic and funding reasons are often too expensive and/or too difficult to sue.
- a tax placed on profits of mesh medical device products at a rate that relates to the severity and frequency of adverse reactions.

## 12: Ensure transparency of this independent Review

12.1 Review to be independent of any medical professional who is involved in the implanting or explanting of pelvic mesh devices.

12.2 Any medical professional who has previously received payment in kind from a pelvic mesh manufacturer should not take part in this Review.

12.3 Ensure the medical profession, particularly O&G and Urology, are aware of the Review and to publicise evidence gathering public meetings.

# Sling The Mesh References

https://slingthemesh.wordpress.com/research-articles/

**1. Government Mesh Audit 2018 Limitations**

Professor Carl Heneghan This is a "seriously difficult report to understand" and there are "several limitations." https://www.cebm.net/2018/04/tape-or-mesh-the-take-home-messages/

- Costs to the NHS are considerable, and the costs outlined underestimate the true costs.
- Costs to women are not included – no information on quality of life and long-term morbidity.
- The report does tell us that the long-term complications persist and worsen over time.

NHS Digital Mesh Audit report https://digital.nhs.uk/data-and-information/publications/statistical/mesh/apr08-mar17/retrospective-review-of-surgery-for-vaginal-prolapse-and-stress-urinary-incontinence-using-tape-or-mesh-copy

**2. The Need for Unbiased Long Term Research into Efficacy and Safety ignored in UK**

In 2003 a Health Technology Assessment said long-term efficacy and risks of TVT were not known. Further research suggestions include:

- unbiased assessments of longer term performance from follow-up of controlled trials or population-based registries;
- more data from methodologically sound RCTs using standard outcome measures;
- a surveillance system to detect longer term complications, if any, associated with the use of tape;
- and rigorous evaluation before extending the use of TVT to women who are currently managed non-surgically.
- These recommendations were largely ignored and watered down in the 2003 NICE guidelines. None of the recommendations were acted on. https://slingthemesh.files.wordpress.com/2018/01/health-techmnology-assessment-mid-urethral-slings.pdf

BAUS response to NHS England interim working group report from 2015:

BAUS response includes many ideas to strengthen up protection for women and also develop more robust reporting systems.

https://www.baus.org.uk/_userfiles/pages/files/professionals/sections/female/Response%2

0to%20NHS%20England%20mesh%20recommendations.pdf

Swedish study shows mesh complications can occur 11 years after implantation. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4491931/

Most reports do not follow up women after one year. Mesh complications can take months or years to occur. Chronic pain risk could be as high as 31%. Risk of bladder perforation 31% (Ackerman and Raz 2016) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5006757/

Linda Cardozo said in 2005 that slings need more randomised, controlled trials and follow up for 5 years. https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/j.1471-0528.2000.tb11683.x

Linda Cardozo has stated that treatment is shifting from secondary to primary care

https://slingthemesh.files.wordpress.com/2018/03/mesh-surgical-care-for-sui-protocol.pdf

In 2016 the International Urogynecology Journal reported in a study

"clinicians are making decisions about surgical intervention for SUI based on follow- up as short as only a few months, while most women will live for many years following an SUI procedure"

https://link.springer.com/article/10.1007/s00192-015-2902-7

**3.Failings in adverse event reporting**

**3.1 MHRA**

Patient safety alert issued in 2014 highlights the lack of auditing of all medical devices.

https://slingthemesh.files.wordpress.com/2017/12/mhra-safe-from-harm-psa-med-dev-0414.pdf

- 82.3% of doctors did not record manufacturer.
- 65% did not record product name
- 68.1% did not record causes of a patient problem.
- 40% did not record outcomes because it was wrongly coded including death or serious harm.
- MHRA admit that there are austerity measures in the medical device department. https://www.pmguk.co.uk/data/page_files/publications%20and%20reports/2014/con40

2542.pdf

- The MHRA and NHS mesh risk figure is 1-3%, but it only includes complications of pain and erosion, not painful sex / lost sex life, which it states is 13.5%. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/213189/vaginal-tapes-and-meshes-letter-to-NHS-final1.pdf
- Only 27% of surgeons report all of their mesh removals to the MHRA database because it is not mandatory to do so. (Duckett et al) https://link.springer.com/article/10.1007/s00192-016-3217-z

- Surgeons do not report adverse events with medical devices because they do not see the point. Except by not recording problems nobody gets to see the true risk rate. Urback et al in BMJ http://qualitysafety.bmj.com/content/early/2017/08/02/bmjqs-2017-006481
- BMJ Article by Mary Madden who asked the MHRA whether they should have stricter controls on medical devices.

**3.2 BSUG Audit of Mesh Complications – Data Base Scandal**

- The March 2018 BSUG newsletter announced the arrival of these audit results but by June 2018 they are still not online. https://mailchi.mp/d8db55a31f18/bsug-newsletter-march-2018 )

- Companies House show the BSUG database was dissolved on October 14, 2014. Two months after the deadline to submit to the BSUG audit. https://beta.companieshouse.gov.uk/company/06839139

- Consultants cannot add mesh complications if the mesh implant surgery was done by another surgeon. Results in vast numbers of complications not logged. (https://slingthemesh.files.wordpress.com/2018/06/recording-mesh-graft-complication-surgery-on-the-bsug-database.pdf )
- BMJ study Participants perceived Adverse Medical Device Event (ADME) reporting as unnecessary, not possible or futile. Physicians were not motivated to report AMDEs because they viewed them as an expected or unavoidable part of practice that they themselves could manage by switching to different devices or by developing work-around strategies to continue using problematic devices. Device industry factors (no feedback to reports of AMDEs, little impact on device improvement) and healthcare system capacity (lack of systems for AMDE reporting, lack of patient monitoring for AMDEs, poor patient record of devices used, purchasing contracts constrain device choice) reinforced individual physician views and behaviour. As a result, some physicians used devices that were less than ideal for a given patient or with which they were unfamiliar, potentially leading to poor patient outcomes. https://qualitysafety.bmj.com/content/early/2017/08/02/bmjqs-2017-006481

- International surgeon societies shame BSUG for failing to report mesh incidents to their database AS LONG AGO AS 2010 The ICS IUGA meeting in Canada calls out BSUG for failing to report to their databases as per NICE guidelines. ( http://bsug.org.uk/userfiles/file/audit-database/ICS Abst Meshes V8.pdf )

- BSUG ask J&J for £20,000 funding for its database in 2010

(https://slingthemesh.files.wordpress.com/2018/01/bsugcommitteemeetingminutesjan2010.pdf)

**4. Safety of Mesh Warnings Ignored from 2004 - 2017**

- Plastic mesh for prolapse repair should be abandoned. Mesh increased Dyspareunia by 20%. 13% had vaginal erosion. High rate of morbidity. (Milani et al 2004) https://obgyn.onlinelibrary.wiley.com/doi/abs/10.1111/j.1471-0528.2004.00332.x
- Mazouni et al. (2004) 26.5% have reduced sexual dysfunction after TVT https://www.nature.com/articles/nrurol.2014.205?foxtrotcallback=true
- 2007 warning ignored. Many products are used despite limited scrutiny or long-term efficacy checks https://www.tandfonline.com/doi/pdf/10.1586/17434440.4.5.675?needAccess=true
- Marszalek et al 2007. Risk of reduced or lost of sex life is 14.3% https://www.ncbi.nlm.nih.gov/m/pubmed/17293651/
- See also https://www.tandfonline.com/doi/pdf/10.1586/17434440.4.5.675?needAccess=true&
- Mesh kits do not make ethical sense. Before mesh kits, there was little commercial interest in gynaecological surgery but operation-specific kits provided almost everything you need to operate except good clinical judgment and technical skill (Wall and Brown 2009) https://link.springer.com/article/10.1007/s00192-009-0985-8
- "Almost two decades after the introduction of TVT and midurethral slings into clinical practice, and by any modern industrial standards of quality, a 30–40% rate of adverse events is simply unacceptable." Firouz Daneshgari 2012 https://www.europeanurology.com/article/S0302-2838(12)00235-7/pdf?code=eururo-site
- 2014 study of 347 women with complications showed 30% had dyspareunia, 42.7% had mesh erosion and 34.6% had vaginal pain. 77% had a severe complication requiring further surgery. American Journal of Obstetrics and Gynaecology AJOG (Abbot et al) https://slingthemesh.files.wordpress.com/2017/04/mesh-60-77-mesh-complications-requiring-further-surgery-1.pdf
- Incontinence mesh risk is 12% - 2017 European Urology (Chapple et al) https://www.europeanurology.com/article/S0302-2838(17)30279-8/pdf
- Keltie & Elneil Landmark Study – Published in 'Nature'

http://www.cambstimes.co.uk/news/mesh-womens-health-hospital-vagina-scotland-sling-the-mesh-1-5217787

- Mesh risk is AT LEAST 10%
- > 92,000 women included over an eight-year period.
- 10% of women attend hospital for mesh complications

Sue Ross1, Selphee Tang1, Misha Eliasziw, Doug Lier, Isabelle Girard1, Erin Brennand1, Lorel Dederer, Philip Jacobs, Magali Robert

https://link.springer.com/article/10.1007/s00192-015-2902-7

- 27.6% suffer complications following a TVT and 21.8% for a TOT..
- "Serious adverse events and tape effectiveness did not differ between groups at 5 years." truth is all mesh has serious risk regardless of whether it is TVT, TVTO or TOT.
- Risk of negative outcome from incontinence mesh is 15% and plastic degrades

- Risk of reduced or lost sex life is 26.5%

Alison et al

https://journals.lww.com/greenjournal/Abstract/2018/03000/Delayed_Presentation_of_Cecal_Perforation_With.13.aspx

- Evidence for bowel injury as a postoperative TVT complication even after 1 year
- Risk can be life changing and irreversible

Fabian et al

https://slingthemesh.files.wordpress.com/2018/06/complicatoins-of-mesh-slings-40.pdf

- Risk of suffering complications after mesh is 40%
- Pain, erosion, failure to fix the problem, De Novo urgency, bleeding, post operative voiding dysfunction, bladder perforation, abscess, haematoma

Duckett et al

- Findings showed Miniarc mini slings don't work (study funded by manufacturer AMS) http://link.springer.com/article/10.1007/s00192-013-2125-8

Hampel Study

https://www.europeanurology.com/article/S0302-2838(17)30334-2/fulltext

- German surgeons "remain unimpressed." that traditional surgery skills to fix prolapse and SUI have been lost to mesh without evidence to support the claim it is a cheap, quick fix.
- Figures massaged to fit desired outcomes.

Knoedler et al

- one in five women need re operation after prolapse mesh. A total of 34% had mesh poking through/extruding through vaginal walls and 16% say they were very unsatisfied with the operation.

Iglesia et al

- Risk of prolapse mesh cutting into tissue, nerves, muscle, vaginal walls 15.6%
- Risk of incontinence mesh doing so is 27.6%

https://journals.lww.com/greenjournal/Fulltext/2010/08000/vaginal_Mesh_for_Prolapse__A_Randomized_Controlled.9.aspx

Lenore, Ackerman and Shlomo Rax

- Looking at a range of literature concluded synthetic slings are not safe.
- Mesh erosion varies widely from 0–33%.
- The average incidence of graft erosion is 10.3%. Other studies say it is 0–7.3%.

- Yet another study shows it is 0–21% for POP surgeries.
- This review illustrates no one knows the true scale of the mesh scandal

http://www.intbrazjurol.com.br/pdf/vol42n04/Difference_of_opinion_640_644.pdf

Donna Y. Deng , Matthew Rutman ,Shlomo Raz , Larissa V. Rodriguez , 5 December 2006

- Major complications of midurethral slings are more common than appear in literature.
- Devastating complications involving urethral and bladder perforations can present with mild urinary symptoms and thus are likely under-diagnosed and under-reported.
- Most of these cases need to be managed with additional reconstructive surgery.

https://onlinelibrary.wiley.com/doi/abs/10.1002/nau.20357

Rapoport, Fenster, Wright

- 22.3% risk of suffering painful UTIs after TVT
- 19.7% risk of urinary retention.

https://www.bcmj.org/search-page?search_api_views_fulltext=sites%20default%20files%20BCMJ%2049%20Vol9%20reported%20complications%20pdf

Margolis - Single incision mini tape study

- Mesh benefits do not outweigh risks

https://www.bcmj.org/search-page?search_api_views_fulltext=sites%20default%20files%20BCMJ%2049%20Vol9%20reported%20complications%20pdf

Hilton et al

- 20% experienced mesh complications, half of which were considered to be serious.
- At 2 years following insertion only 10% were cured

https://obgyn.onlinelibrary.wiley.com/doi/abs/10.1111/j.1471-0528.2009.02449.x

European Urology – TVT Secur 2010 Study

- Only a 31% success rate after a 4.5-yr of follow-up.
- Removed from market in 2013.

https://www.europeanurology.com/article/S0302-2838(12)00768-3/pdf

- Contradicts an earlier 2009 UK TVT Secur study which said it is safe with low complication rates

https://slingthemesh.files.wordpress.com/2018/01/tvt-secur-good-results-in-uk-doesnt-

tally.pdf

Andrew Siegel, November 2005

- The Mentor ObTape sling, which uses a nonwoven, minimally elastic, micropore, monofilament polypropylene mesh, incurs an unacceptably high rate of defective vaginal wound healing and mesh extrusion.

https://www.goldjournal.net/article/S0090-4295(05)00652-7/abstract

Hilton and Rose

- Mesh implants are over used which means the skills to perform a traditional surgical fix are being lost.
- "Whilst seductively simple in concept, mid-urethral tape procedures are not without risk."
- "Their inherently "blind" nature makes them difficult to teach. The "learning curve" to independent practice may be longer than previously considered."

https://link.springer.com/article/10.1007/s00192-015-2853-z

- It is a steep learning curve to teach how to insert mid urethral slings. Meanwhile, however, women are being injured.

https://www.ncbi.nlm.nih.gov/pubmed/24793930

Abbott

- Most women who seek management of synthetic mesh complications after POP or SUI surgery have severe complications that require surgical intervention.
- A significant proportion require more than one surgical procedure.
- 305 of them have lost sex lives and 42.7% had erosion.

https://www.ncbi.nlm.nih.gov/pubmed/24126300

Prospect Study

- Vaginal repair for prolapse with mesh or graft material did not improve women's outcomes in terms of effectiveness, quality of life, adverse effects, or any other outcome in the short term.
- 12% of women had a complication.
- The implantation of any mesh for the treatment of prolapse via the vaginal route should be only considered in complex cases in particular after failed primary repair.

https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)31596-3.pdf

Lee et al – Researchgate Transvaginal Mesh

- Complications are serious and most not reversible.
- https://www.researchgate.net/publication/233827273_Transvaginal_Mesh_Kits-How_Serious_Are_the_Complications_and_Are_They_Reversible

Kokanali et al

- Women's pain and complications are not taken seriously even in the studies. In this study it says mesh erosion following vaginal sling procedures is a frustrating complication with relatively low incidence.
- https://www.ncbi.nlm.nih.gov/pubmed/24793930

Dunn et al

- Women describe a feeling of hopelessness and abandonment after suffering mesh complications.
- https://www.ncbi.nlm.nih.gov/pubmed/24793930

Hanne Christensen, Herlev Hospital, University of Copenhagen and Thomas Bjarnsholt, of University of Copenhagen

- True incidence of complications is not known, as fewer than 25% of patients return with their sling problems to the same surgeon.
- Under reporting is a major issue
- http://ec.europa.eu/health/scientific_committees/emerging/docs/surgical_co_christensen.pdf

Shah Badlani et al

- This study gives widely varying figures for mesh erosion – 0-33%
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3424888/

Trial of mini slings at St Mary's Manchester:

https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/j.1471-0528.2009.02449.x

- 20% failure rate within one month.
- 20% of the 60 participants had mesh complications.
- Only 10% still cured at 2 yrs.
- 38% (41 out of 60) left study to to have other surgical procedures for SUI .
- Technically that's also a complication to be reported to the MHRA as a surgical reoperation/revision was needed. So the complication rate should be over 30%
- Some refused to come back & participate.
- Only 19 women completed the 2 yr follow up period.
- Why wasn't this trial terminated?

Audit by Price and Jackson – Oxford

https://pdfs.semanticscholar.org/6a03/4e36e3b26b90d3d5a185f7e862e2f2fa7bc7.pdf

- 27% of women need to self catheterise after TVT mesh tape
- 57.9 % had this mesh as primary surgery
- 41.6% had it for failed previous SUI surgery

Mini Slings failed for nine out of ten women in Manchester

https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/j.1471-0528.2009.02449.x

- UK experimental mesh trials resulted in serious complications for women.
- 90% **mesh** tape failed at St Marys Manchester & Royal Victoria Hosp Newcastle.
- Only 10% Cured.
- 38% needed more surgery.
- Not enough surgeons with skills to remove mesh.

Treatments for SUI depends on surgeon opinion not on evidence based research

https://link.springer.com/article/10.1007%2Fs00192-017-3376-6

- No consensus exists amongst surgeons for treatment of recurrent SUI
- However, many surgeons say they would put another mesh sling in if the first one fails

BJOG "The rise and fall of vaginal mesh" https://obgyn.onlinelibrary.wiley.com/doi/pdf/10.1111/1471-0528.12927

BJOG IUJ "The patient is the one who has most to lose in this debate" https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4987386/

Study shows tumour like reaction inside the vagina following a polypropylene TVT sling

(http://www.hinawi.com/journals/criog/2017/6701643)

Yeni et al Study – International Urogynecology Journal (Dec 2003)

https://link.springer.com/article/10.1007%2Fs00192-003-1100-1

- TVT can result in women losing or suffering reduced sex lives.
- Women should be counseled about this.
- 1 in 4 women lose or have reduced sex lived because of mesh.

https://www.nature.com/articles/nrurol.2014.205?foxtrotcallback=true

EJOG "Prolapse surgery worsens sex life concerns"
https://www.ejog.org/article/S0301-2115(16)31024-7/fulltext

The authors reported when followed for up to 25 years, almost one third of patients who had a mesh augmented transvaginal repair of prolapse required a subsequent operation. Over 20% of patients required reoperation for a mesh related complication.

SUFU 2018: Meshing Around: Long-Term Outcomes Following Vaginal Reconstructive Surgery with Synthetic Mesh Augmentation

**5. Science of plastic: Dangers of Implanting polypropylene plastic into the Body**

- Three independent reports by plastics expert Chris DeArmitt, a consultant to Fortune 100

  https://slingthemesh.files.wordpress.com/2018/05/phantom-plastics-mostyn-law-pp-mesh-design-report-final-cd-2018.pdf

  https://slingthemesh.files.wordpress.com/2018/05/boston-scientifics-expert-rebuttal-report-v2018-redacted-2.pdf

  https://slingthemesh.files.wordpress.com/2018/05/boston-scientifics-expert-rebuttal-report-v2018-redacted-2.pdf

- Foreign body reactions to implants can be "devastating" says this study.
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2327202/

- All types of Polypropylene mesh degrade in body. 1 in 10 people have to have their mesh removed because of complications. https://www.ncbi.nlm.nih.gov/pubmed/26315946
- vaginal pain risk from mesh contraction is a serious complication (Feiner et al) https://www.ncbi.nlm.nih.gov/pubmed/20093906

- Scar tissue causes mesh to contract to less than half its implanted size. This causes dyspareunia, vaginal pain and erosion into adjacent organs. An individual response in fibrosis also exists, with some individuals being "high responders." Polypropylene is not inert within the human body.(Ostergard 2010) https://www.ncbi.nlm.nih.gov/pubmed/20859162
- A microscopic analysis of meshes explanted from patients showed mesh degrades and can turn brittle inside the body. Vladimir V. Iakovlev, Scott A. Guelcher and Robert Bendavid. https://slingthemesh.files.wordpress.com/2018/03/iakovlev_bendavid-et_al-2015-journal_of_biomedical_materials_research_part_b-_applied_biomaterials.pdf

- Polymers are toxic and plastic degrades. Many properties of polypropylene mesh, causing complications for patients, were published in the literature prior to the marketing of most currently used mesh configurations and mesh kits. These factors were not properly taken into account before selling these products. https://link.springer.com/content/pdf/10.1007%2Fs00192-011-1399-y.pdf

- The Definitive User's Guide and Databook by Clive Maier, Theresa Calafut shows that polymers are potentially toxic substances that should not be used in medical devices.

- Polypropylene plastic used to make mesh implants can leach toxins and break down under body heat once implanted. This study shows chemicals with unknown toxicity form when polypropylene plastic is heated – study by Reingruber, E, M Himmelsbach, C Sauer and W Buchberger. 2010. https://searcymasstort.com/blog/polypropylene-under-heat-releases-toxic-chemicals/

- AJOG In women with complications, mesh induces a proinflammatory response that persists years after implantation. Removed meshes show degradation; and pain is consistent with fibrosis. https://www.ajog.org/article/S0002-9378%2816%2930049-7/fulltext#.Wftcz4z9gac.twitter

- Rogowski et al found an ongoing reduction in the mesh size – they found it can shrink up to 53%. https://www.ncbi.nlm.nih.gov/labs/articles/23749240/

- European Association of Urology 2013 Beyond the current, passionate debates for or against synthetic material, there is limited knowledge about the long-term integration of these devices into the vaginal wall near vital adjacent organs and the risks and benefits of the devices' added strength versus native tissue repair. http://www.tvt-messed-up-mesh.org.uk/pdfs/Mesh-Sling-in-an-Era-of-Uncertainty-Lessons-Learned-and-the-Way-Forward.pdf

- Complications from polypropylene mesh:
  http://ec.europa.eu/health/scientific_committees/emerging/docs/surgical_co_christensen.pdf

  - https://chemicals.news/2017-11-30-polypropylene-toxicity-side-effects-diseases-and-environmental-impacts.html

  - https://www.medicinenet.com/plastic/article.htm#what_is_polystyrene_ps

  - https://www.creativemechanisms.com/blog/all-about-polypropylene-pp-plastic

- Hernia:
  https://www.researchgate.net/publication/264859946_Mesh-Related_SIN_Syndrome_A_Surreptitious_Irreversible_Neuralgia_and_Its_Morphologic_Background_in_the_Etiology_of_Post-Herniorrhaphy_Pain

**6. Lack of Patient Informed Consent & Aggressive Marketing**

- Surgeons are not properly informing patients about risks
- Complications are under-reported.
- Even with complete mesh removal, more than 30 per cent of patients may be permanently disabled.

http://tvt-messed-up-mesh.org.uk/pdfs/Mesh-Sling-in-an-Era-of-Uncertainty-Lessons-Learned-and-the-Way-Forward.pdf

- Welsh women were not given patient information leaflets for prolapse operations using mesh from 2006 to 2011. How is this fully informed consent? https://www.ics.org/Abstracts/Publish/180/000250.pdf

- Aggressive marketing of drugs and devices is a real issue – and it's more than just a free lunch.

https://www.youtube.com/watch?v=YQZ2UeOTO3I&feature=youtu.be

- Ethicon release brochure with risks of mesh but those risks are not included in UK patient information leaflets See P6. Risks of exposure, infection, pain, foreign body reaction, fistula, urinary tract obstruction.

https://www.ethicon.com/sites/default/files/managed-documents/031295-150316_tvt_patient_brochure11_cr_0.pdf

- Ethicon co sponsor a study, published in a prestigious American medical journal, to show prolapse mesh in a favourable light. See http://meshcomplications.com/files/2014/09/Mesh-deicisions-4264934-4287872.pdf
- Ethicon employees give evidence in mesh trials. Link courtesy of leading lawyers Mazie, Slater, Katz and Freeman. http://meshcomplications.com/

**7. Limitations and Failings in Mesh Trials**

- Early trials on animals proved mesh implants cured the problem but did not show the devastating complications mesh can cause.
- Many studies were short term.
- Many trials use woefully low patient numbers making it difficult to capture a clear picture of risk
- Report authors conflicts of interest means studies have a high risk of bias.
- There is p hacking which is medical speak for research fraud where figures are massaged to fit desired outcomes by amending trial protocol.
- Research questionnaires are not designed to capture worsening or new onset complications
- A woman could be a wheelchair user, having had multiple mesh removals and in terrible pain, but if the mesh has fixed her incontinence then in trial terms she is deemed a success.
- In the Single Incision Mini Sling (SIMS) trials, the questionnaire shows that medics do not fully allow women to report their quality of life complications. http://www.wisbechstandard.co.uk/news/mum-of-three-leaks-documents-to-sling-the-mesh-campaign-to-show-that-pain-suffered-after-her-operation-is-being-ignored-despite-being-part-of-a-trial-that-promised-to-monitor-her-for-three-years-1-4160667

- The Nilsson TVT study often quoted by manufacturers, used just 90 women but dropped

to 56 at the end of the 17 years and 12 of those were interviewed over the phone. 11 women died. The two leading trial authors were paid Ethicon consultants. Yet still this study is used to "prove" mesh is safe globally.

https://www.researchgate.net/publication/11890647_Long-term_Results_of_the_Tension-Free_vaginal_Tape_TVT_Procedure_for_Surgical_Treatment_of_Female_Stress_Urinary_Incontinence

https://www.ncbi.nlm.nih.gov/pubmed/15572486

https://www.ncbi.nlm.nih.gov/pubmed/18535753

https://www.ncbi.nlm.nih.gov/pubmed/23563892

- Only 3% of 120,000 women given mesh are recorded anywhere. Reviews are poor quality and do not provide meaningful results. https://link.springer.com/content/pdf/10.1007%2Fs00192-009-0927-5.pdf
- Randomised Controlled trials (RCTs) compare one type of mesh to another as oppose to mesh versus a natural tissue repair.
- A crisis of confidence in evidence base. There are 40,000 clinical trials Ethics, regulation, research bodies and conflicts of interests are a concern across the entire medical device and pharmaceutical industry. https://www.bmj.com/content/357/bmj.j2973
- Yeng, Raz et al Mesh risks are devastating and happen more frequently than appear in the literature https://onlinelibrary.wiley.com/doi/abs/10.1002/nau.20357
- Anzjog Journal –"Transvaginal mesh let's not repeat the mistakes of the past." https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/ajo.12597
- < 40% of surgeons report mesh complications to the main BSUG database and do not include loss of sex life to help keep the figure low.
- Dozens of recent clinical trials may contain wrong or falsified data. The Guardian's John Carlisle's review into falsified trials. https://www.theguardian.com/science/2017/jun/05/dozens-of-recent-clinical-trials-contain-wrong-or-falsified-data-claims-study?CMP=Share_iOSApp_Other
- A report published in The Lancet gives the impression that it follows women for 18 years from 1997 to 2016. It doesn't. It only follows women for up to five years but takes statistics from an 18 year period. The statistics used are called Hospital Episode Statistics HES. They only record women attending hospital for a mesh complications. They don't include repeat GP visits for painkillers, antibiotics for urinary infections. HES data vastly under reports mesh complications. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)32572-7/supplemental
- Nilsson study said it followed women for 17 years. Only 70 out of 90 women agreed to a final interview. It claims one woman had a mesh exposure and no other complications occurred. Two of the medics involved in this study had financial interests with the mesh manufacturers. At 11 years the study claimed no conflicts of interest, but at 17 years stated there were. (2008) https://www.ncbi.nlm.nih.gov/pubmed/23563892

- Schimpf et al found erosion risk for prolapse mesh is 36% but said re-operation rates were low. This study clearly shows that researchers see the initial prolapse problem has been fixed, but ignore complications. https://www.ncbi.nlm.nih.gov/labs/articles/27275813/
- K Baessler. Mesh is a good fix as in anatomical outcomes but vaginal floor symptoms are scarcely reported in reviewed trials, so how does anybody really know quality of life after a mesh implant?
  https://www.ncbi.nlm.nih.gov/labs/articles/22083097/

- 38% of women leave a study by Hilton to have surgery, but the study does not mention this in the conclusion. https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/j.1471-0528.2009.02449.x
- Barski et al There has been no randomised trials on mesh complications.
  https://www.hindawi.com/journals/bmri/2015/831285/

"New Mesh" – UK Trial ongoing

( https://clinicaltrials.gov/ct2/show/NCT02407145 )

- Shrinkage with the polypropylene mesh is admitted as a problem.
- Mesh trial of DynaMesh®SIS soft, made of polyvinylidene fluoride (PVDF) which reports improved biocompatibility for reduced scar formation and less mesh shrinkage.
- It is still plastic and still introduces a foreign body into a clean, contaminated field using large hooks and inserted blindly.
- Inadequate short-term follow up: one year then, then for a further year by postal questionnaire. Clinical follow up is at 3 and 12 months post operatively and as required if any concerns.
- A lawyer in the USA has called for a criminal investigation into Johnson and Johnson after it was found thousands of documents were destroyed and hard drives wiped clean with information relating to mesh implants.
  https://www.youtube.com/watch?v=UE5zKgI9-m8

TVT Secur was not getting good results in the studies but Douglas Tincello, of Leicester, wanted to run a trial of it. Short-term 93.5% success. Long-term only 40% patients cured & 42% failed. It was quietly taken off the market in 2012.

https://www.sciencedirect.com/science/article/pii/S0302283810003696

**VUE Trial**

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5016955/pdf/13063_2016_Article_1576.pdf … .

- Started 2013 across 40 centers.
- Six month and 12 month reviews completed.
- Not even 12 month results have been published.
- Full results should have been published by February 2018.

**8. Conflicts of Interest**

The Cochrane Review looked at 81 mesh trials and found only two were at low risk of bias. A total of 13 were high risk and in the other 66, bias was unclear. http://www.wisbechstandard.co.uk/news/women-have-reported-serious-and-debilitating-problems-following-an-operation-for-incontinence-often-caused-by-childbirth-1-4136556

Conflicts of interest mean studies are at a high risk of bias because the authors have received payments in kind from the medical device manufacturers. The following examples illustrate this: -

- In a May 2017 study, the author says there is no link between surgical mesh and autoimmune conditions like fibromylagia or cancer. See study and link to Industry payments.
  https://www.practiceupdate.com/news/15976/32/3?elsca1=emc_conf_AUA2017During-1&elsca2=email&elsca3=practiceupdate_uro&elsca4=201742_AUA2017During-1&elsca5=conference&rid=MTc4MDkxNzExOTYwS0&lid=10332481

  https://openpaymentsdata.cms.gov/physician/1301041/summary

- Surgeon Vincent Lucente bragged in 2007 that he encouraged an American surgeon society to remove the word "experimental" from its literature about a new prolapse mesh kit by Ethicon because it would scare people off. At the time he was the highest paid trainer of other surgeons by Ethicon.
  https://www.fpminstitute.com/about_us/lucente.phtml
  https://openpaymentsdata.cms.gov/physician/30143/summary

NB In the UK there is only a voluntary conflicts of interests list. http://www.whopaysthisdoctor.org/doctors

- A study headed by Linda Brubaker shows adverse episodes occur for up to 42% of women following a mesh sling implant for incontinence. It says 20% of complications are serious. Yet the authors say mesh is still acceptable to use. There are 11 authors and only five declare "No Conflict of Interest" The other six are all MDs except for Yan XU who has a Master's degree. Among the non-declared conflicts of interest (COI), Gary Lemack received $136 832 in 2013-2015. To check his COI visit this site. This paper claims pain beyond six weeks was 2.3%, which seems unlikely. This same TOMUS study is followed up after 5 years, but strangely the adverse events suddenly fall to 10% Also in this study the efficacy says it is only 51.3% which means a failure rate of 48.7%. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3205289/

- Mesh triggers autoimmune disease (e.g. fibromyalgia and lichens schlerosis). A study in 2017 by Chughtai found no link between mesh and auto immune conditions. Chughtai received around $140,000 in payments in the year before this study was published. https://www.practiceupdate.com/news/15976/32/3?elsca1=emc_conf_AUA2017During-1&elsca2=email&elsca3=practiceupdate_uro&elsca4=201742_AUA2017During-1&elsca5=conference&rid=MTc4MDkxNzExOTYwS0&lid=10332481

  https://openpaymentsdata.cms.gov/physician/1301041/summary

- Report by Wall and Brown looks at what happens when commercial interest drives surgery 2009. https://link.springer.com/article/10.1007/s00192-009-1003-x

- Peter Angelos "To uphold professionalism, surgeons must be driven by altruistic motives rather than self-interest. They must not allow the lure of the new and potential for financial benefit to influence their assessment of whether an innovative procedure truly benefits the patient."
  https://assets.documentcloud.org/documents/3924306/Mesh-Doc-2.pdf?fref=gc

  https://assets.documentcloud.org/documents/3923201/Mesh-DOC-1.pdf?fref=gc

- The Bradford Institute for Health Research on ethics approval in the UK, states that approval is key to: -

  - Ensuring that the Study is managed, monitored and reported as agreed in the Protocol.

  - Ensuring that no Participant is recruited to the Study until the PI is satisfied that all relevant regulatory permissions and approvals have been obtained.

  http://www.bradfordresearch.nhs.uk/for-researchers-and-staff/initiation-delivery/delivery/conduct-amendments-urgent-safety-measures

**9. Inadequacies of NHS Mesh Removal Centers**

https://bsug.org.uk/budcms/includes/kcfinder/upload/files/BSUG%20news%20letter.pdf

- In a BSUG newsletter from 2017 they admit being a mesh centre is not an endorsement of competence. It just means they meet set criteria.
- Only 3 Translabial scans available in UK to identify mesh
- Waiting lists grow while women's complications worsen.
- Surgeons globally are slowly waking up to the fact that mesh has high risks. Few surgeons can successfully remove the plastic implants once mesh is embedded into a woman's vaginal tissue after 6 weeks.
  https://search.proquest.com/openview/4b61ae9c928f3a4d49092b305896d8ec/1?pq-

origsite=gscholar&cbl=326303 )

**10. Mesh Risks Upgraded in EU and USA**

- Mesh to be upgraded to a higher risk medical device in the EU by 2020. See pages 469/70. http://data.consilium.europa.eu/doc/document/ST-10728-2016-INIT/en/pdf
- FDA in USA says the implanting hooks are high risk and upgrades (hooks) to implant vaginal mesh implants, to a higher risk device. https://www.federalregister.gov/documents/2017/01/06/2016-31862/obstetrical-and-gynecological-devices-reclassification-of-surgical-instrumentation-for-use-with

**11. Private Earnings for Surgeons**

- Surgeons can make an additional 1/3 of their NHS salary from private practice.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2442143

**12. Lack of trained and experienced surgeons in full mesh removal**

Managing mesh complications: STM response to this report is that if it is so difficult to fully remove mesh, only partial mesh removals, then why are surgeons implanting something that can not be fully removed. Patients are guinea pigs. Cundiff and Slack_et_al-2018-BJOG_Managing mesh complications

**13. See also Mesh Medical Device News Desk**

For up to date developments worldwide.

https://www.meshmedicaldevicenewsdesk.com/

**Current Situation**

1. From 2005 to 2015 almost 7000 women in N Ireland had a mesh implant inserted. The numbers before this time are unknown however it is known that some women had mesh implanted as early as 1999
2. The Public Health Agency (PHA) state that POP mesh procedures (vaginally inserted) have not been used in Northern Ireland since 2015 due to life altering and severe complications
3. The PHA say that only TVT insertion remains in common practice while TVTO is now recognized to cause more pain postoperatively and rarely used
4. The experience of most women in N Ireland is very similar to that of women in the rest of the UK. The same issues of lack of informed consent and of complications involving infection, pain, urinary retention or worsening incontinence. Loss of sex life, disability, lost marriages and jobs. Same experience of being fobbed off and of dismissed and being placed on a continuous merry go round of often unnecessary appointments and procedures all considered as mere delay tactics. Women never getting properly diagnosed or being continuously told 'its not the mesh' or that it is fibromyalgia and IBS
5. No experience of mesh removal amongst surgeons in Northern Ireland but plenty of claims of experience that is non existent. Anyone requiring medical treatment outside Northern Ireland must be referred via the ECR process (Extra Contractual Referral). Women asking for ECR are sometimes kept waiting for months by surgeons who have not progressed their requests or by surgeons who have actively blocked the request for some reason or other. At times only when complaints are lodged or solicitors letters sent are the requests progressed
6. No translabial scan. Cystoscopy is the gold standard but as we know is far from perfect where diagnosis of mesh issues is concerned. Growing numbers of women now traveling to England and paying for these scans privately and then paying for a private consultation with a respected and experienced surgeon in England. All these women had been told for years that there were no issues with their mesh implants however the translabial scan easily identified multiple issues that the cystoscopy couldn't possibly visualize. Translabial scan is quick and painless.
7. Several women now electing to pay thousands for private removal in England before they would allow local surgeon near them. Indicative of the lack of trust women now have in their own consultants
8. No reports of mesh complications to MHRA yellow card until August 2016. No one had ever heard of system. No surgeon has ever reported issues either.

Sling the Mesh N Ireland now has over 500 members. Campaign pressure has encouraged the local Public Health Agency to deal with the issue

In September 2017 there was a clinicians workshop held with discussion between clinicians and the PHA about the way forward and in October a group of mesh affected women were

invited to a briefing held by the PHA where plans were announced to create working group to include patient representatives and clinicians. The focus of the working groups were to look at and agree 3 main issues:

- **Patient Pathways** - for women who have had surgery for SUI and POP using vaginally inserted mesh and for those who suffer from these conditions now and in the future to ensure that all women have access to the same kind of good urogynaecological health service regardless of where they live

- **Data collection about clinical practice and patient outcomes** - the need to streamline this issue and quality assure services for women with SUI and POP both before and after treatment

- **Patient information and Informed consent -** review current information leaflets, check lists and consent forms and outline good practice for arriving at informed consent with women considering treatment of SUI

Around 6 patient representatives who applied were elected to take part in the working groups which met between January and March 2018 to produce outputs to try and overcome existing challenges and make recommendations for future service improvements.

The result of these working groups was released earlier this week. Although there are some positive outcomes as in the reintroduction of alternative procedures such as the Burch Colposuspension and the Autologous Sling, improved data capture and more scrutiny on informed consent, Sling the N Ireland do not see these actions as going far enough. Whilst a suspension or ban is not put in place more women are at risk from being harmed from mesh implants. There are no experienced removal surgeons in Northern Ireland and although the PHA love to say that surgeons have been to england to learn we know that this is a case where 2 surgeons travelled to London for one day last November to observe an expert removal surgeon at work. In our view this does not constitute adequate training. Earlier this year Belfast City Hospital was accredited as a unit that would be able to see and treat women with mesh related problems. The lead clinician is Dr Lucia Dolan. A very recent FOI request has revealed that Dr Dolan has no experience in mesh removals and has removed less than 5 TVTs and even these were not full removals. Sling the Mesh NI believe that this alone makes a laughing stock of any so called mesh centre whenever the lead clinician herself cannot adequately deal with the traumatic and often life changing issues that these women are faced with.

*Submitted by STM N Ireland June 2018*

### STM Wales Statement

1st April, 2018, Welsh Government issued a clinical coding change notice, this was due to the current data not being clear on whether the inserted mesh was synthetic (polypropylene) or biological (porcine).

It has not been made clear how or if the Welsh Government will monitor the use of the new coding.

Wales published the findings of the Task and Finish group on 8th May 2018, the full report can be found here:

https://gov.wales/docs/dhss/publications/180504reporten.pdf

Vaughan Gething AM (Cabinet Secretary for Health and Social Care) made some recommendations on how Wales are to proceed, he stated that an implementation group would be set up 'without delay' and will provide progress reports, the implementation group will be chaired by Tracy Myhill, chief executive of Abertawe Bro Morgannwg health board. They are due to meet for the first time in August 2018, three months after the report was published.

Frank Atherton, Welsh CMO, has not made a public announcement on mesh since September 2017.

While some of the recommendations in the report are welcomed (the development of a vaginal care pathway), the token gesture of £1million will not cover a fraction of what the Welsh Government are wanting to happen, there are concerns about how they will implement, monitor and maintain the suggestions now and in the future.

Wales have no specialist mesh centers

Wales have no translabial scan facilities

Welsh GP's have not been given any directive on procedure should a patient present with mesh complications

The Yellow Card Scheme is not widely publicised in Wales

In Wales if we want to be referred to an MDT we must first see a GP, ask for referral to our local gynae/urogynae, quite often this is the surgeon who implanted the mesh originally. If this clinician doesn't think that our symptoms are anything to do with mesh then they refuse to refer us to a specialist, we are then back to square one.

Another problem many of the members of Welsh Mesh Survivors have is refusal of funding for cross border treatment, it can take months for appeals to go through, and then they are often refused again.

If we do manage to get referred to an MDT across border it is WELSH NHS policy that you see the specialist closest to your home address, not necessarily the best specialist for your needs.

Welsh Government say that they are putting 'restrictions' in place with regards to the use of mesh, unfortunately those restrictions haven't been made clear, I have emailed Vaughan Gething to clarify his position since your recommendations to pause/halt mesh in England, Welsh Mesh Survivors have asked for a statement on what. precisely, the restrictions are and how they will implement them, and whether Wales will fall in line with your recommendations. There just isn't enough clear, concise information in place in Wales to protect women against the devastating effects of surgical mesh.

Here is Vaughan Gething's statement dated 11th July 2018, in response to your recommendation to pause the use of mesh

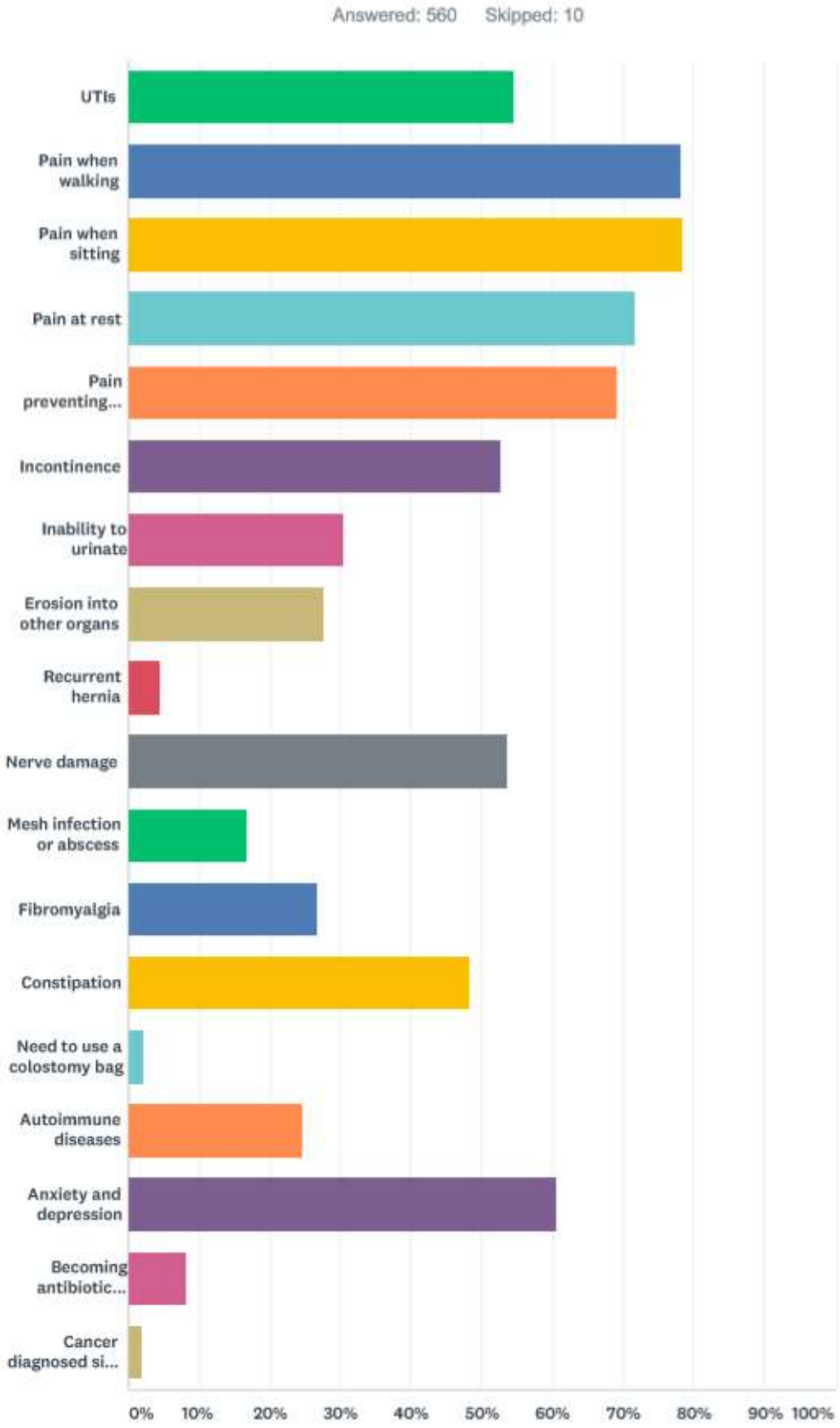
https://gov.wales/about/cabinet/cabinetstatements/2018/bcannouncentonuseofsurgicalmesh/?lang=en

If you would like any further information please don't hesitate to contact me, kpreater@gmail.com

## Annex 2

**Sling the Mesh Survey 2017**

Q3: What types of complications have you experienced since your mesh operation?




**Mesh Implant Complications**

**Sling the Mesh Survey of 570 Women, 2017**

84% of 'Sling the Mesh' survey respondents were not warned of risks.

70% of the respondents who had pelvic mesh, had it implanted for SUI.

| **VAGINAL SUI/ POP**<br><br>**RECTOPEXY MESH COMPLICATIONS** | **CONSEQUENCES**<br><br>**(NB NOT MUTUALLY EXCLUSIVE)** |
|---|---|
| Chronic pain<br><br>80% | - 80% suffer pain which affects daily life<br>- 33% forced to stop work<br>- 20% forced to reduce working hours<br>- 70% lose sex life<br>- reduced mobility<br>- mobility aids required (e.g. scooter, wheelchair, sticks)<br>- consider suicide |
| Pain which affects daily life<br><br>80% | - 78% walking/ sitting<br>-72% resting<br>- 50% have difficulty sitting in vehicles incl. public transport (7% unable to do so)<br>- 63% reduced ability to lift food shopping, cook, clean<br>- 14% unable to lift food shopping, cook, clean<br>- mobility aids required (e.g. scooter, wheelchair, sticks) |
| 53% Incontinence | - e.g. increase or new symptoms of urgency and frequency, SUI, bowel |
| 72% lose sex life<br><br>70% pain on intercourse | - impacts mental health, libido, relationship breakup<br>- |
| 28% suffer Erosion into vaginal walls or organs | - 72% lose sex life<br>- chronic pain<br>- erosion may occur / worsen when menopause thins vaginal walls |

| | |
|---|---|
| 60% Depression & anxiety | - impacts all areas of life<br>- cost to NHS |
| 55% Constant urinary infections | - antibiotic treatment<br>- antibiotic resistance (8%)<br>- death from sepsis |
| 17% Mesh infection or abscess | - Chronic pain<br>- NHS treatment costs |
| 30% unable to urinate properly | - Self catheterise for life<br>- infections<br>- thrush<br>- pain<br>- Costs NHS £1 per catheter |
| 54% suffer strain on relationship with partner/ spouse | - impacts physical and mental health of whole family |
| 15% lose primary relationship | - impacts include, moving home, loss of family income, reliant on state benefits |
| 70% unable to participate in sports/ hobbies<br><br>75% unable to enjoy social life/ hobbies | - weight gain<br>- impacts physical and mental health<br>- social isolation |
| 54% suffer nerve damage | - Chronic pain<br>- deterioration in mobility<br>- mobility aids required (e.g. scooter, wheelchair, sticks) |
| 14% unable to care for their children<br>3% lost their homes | - impact on childrens' health, education etc<br>-impacts family relationships |
| 58% take medication with side effects | - impacts physical and mental health<br>- impacts on daily life |

| | |
|---|---|
| 48% suffer constipation | - increased pain<br>- anal suppositories, laxatives and colonic irrigation required |
| 25% auto immune diseases (e.g. Lupus, arthritis) since mesh | - impacts physical and mental health<br>- impacts on ability to work |
| 27% fibromyalgia | - impacts physical and mental health<br>- ability to work |
| 2% need colostomy bag | |
| 47% paid privately for healthcare for mesh complications | - 7% spent more than £5,000<br>- 3% spent more than £20,000 |
| Mimics oestrogen and increases levels in blood. Releases toxins into body. | - 2% Cancer diagnosis since mesh (including breast cancer) |

**Complications Raised by Women in Narrative Responses in Sling the Mesh Survey of 570 Women, and on the Patient Face Book Group.**

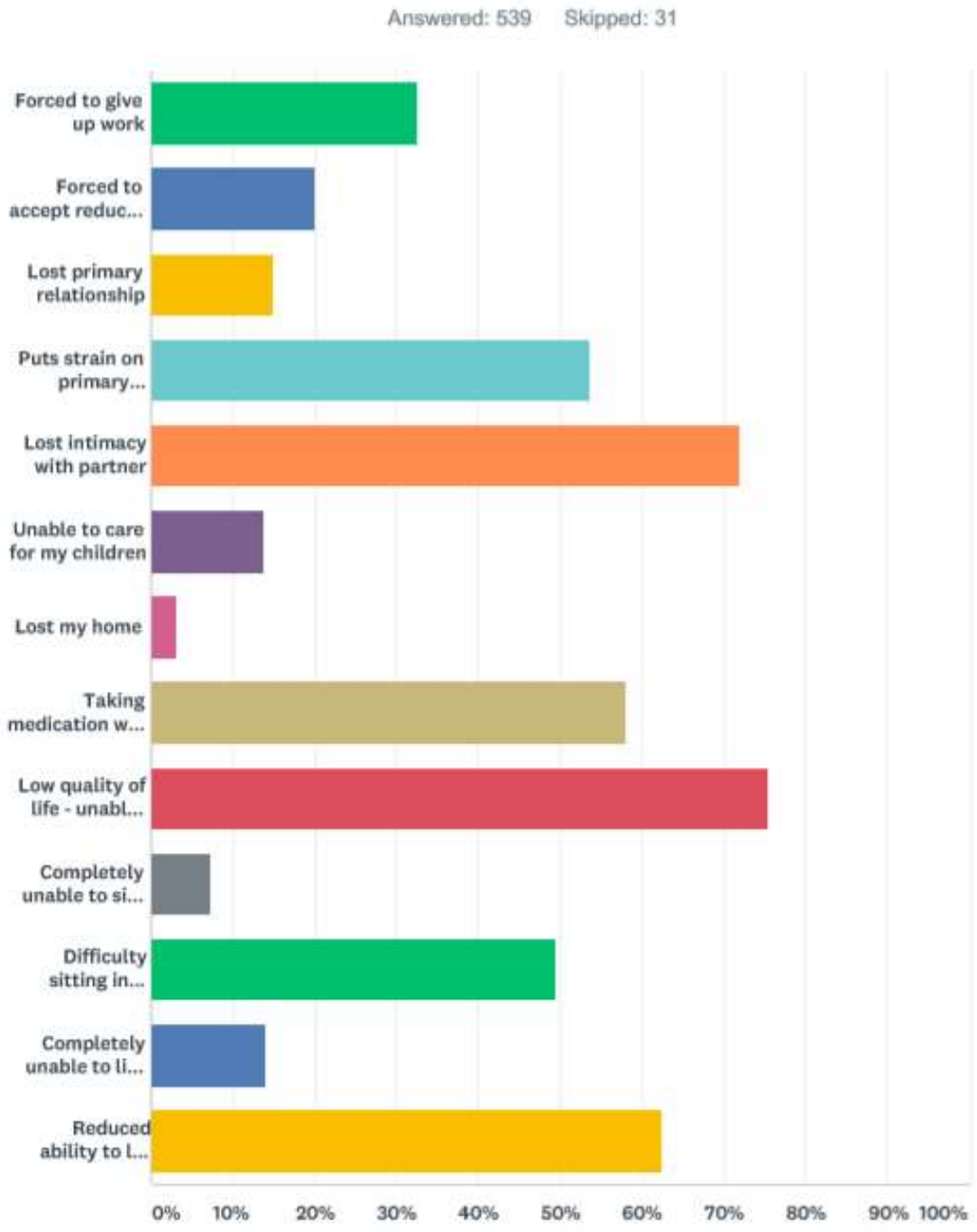
| **VAGINAL SUI/ POP**<br>**RECTOPEXY MESH COMPLICATIONS** | **CONSEQUENCES** |
|---|---|
| foreign body/ giant cell reaction | - sepsis leading to organ failure<br>- cellulitis |
| Inflammation | - pain, |
| hair loss | - confidence |
| swollen stomach | - pain, can't fit into clothes |
| swollen legs | - pain, can't fit into clothes |
| Swollen feet | - pain, can't fit into shoes, walk |
| plantar fasciitis | - pain, can't fit into shoes, walk |
| skin rashes, Psoriasis, eczema, itching | - disappears/ reduces after full mesh removal |
| Scarring | - repetitive thrush |

| | |
|---|---|
| | - painful sex<br>- surgeries to trim scars |
| Obturator & other nerve damage | - Leg, hip, groin, back, buttock, vagina pain<br>- burning pain in vagina, down legs<br>-- mobility aids required (e.g. scooter, wheelchair, sticks) |
| Bladder & Urethra damage | - surgeries to reconstruct |
| UTIs | - become antibiotic resistant, leading to sepsis organ failure and death |
| Kidney function reduced/ kidney failure | - ill health, death |
| Fatty liver | - ill health |
| Thyroid problems | - associated health issues |
| Tinnitus | - disturbed sleep |
| Constant vibration/ buzzing | - only disappears when mesh removed |
| Exhaustion, fatigue | - undiagnosed link to mesh |
| Muscle weakness | - reduced hand grip<br>- unsteady gait<br>- reduced mobility<br>- mobility aids required (e.g. scooter, wheelchair, sticks) |
| Brain fog | - similar impacts as chemotherapy, but permanent |
| Full mesh removaldue to shrinkage, degrading, migrating | - no relief from consequences of complications, but no guarantee of relief even if full mesh removal is achieve |
| Consider suicide | - impact on loved ones |
| Death | - impact on loved ones |

**Annex 3**

**Sling the Mesh Survey 2017**

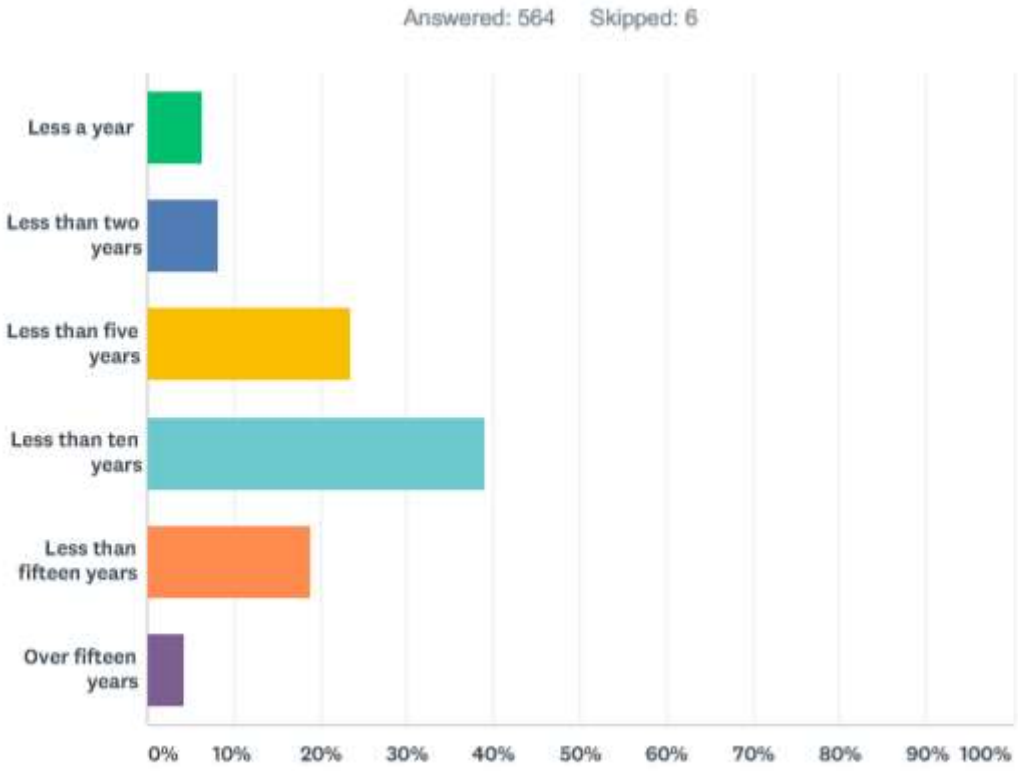
Q7: How have mesh complications affected your life?



**Annex 4**

**Sling the Mesh Survey 2017**

Q4: How long is it since you had your mesh implant?




560 out of 564 STM respondents reported complications from mesh with almost 80% suffering from chronic pain due to erosion into other organs (28%); nerve damage (57%); fibromyalgia (27%) and 61% suffering anxiety and depression. Up to 40% of respondents had their mesh implanted up to 10 years ago and 23.5% up to 5 years ago. This indicates the majority of mesh complications occur or are still ongling years after implantation.

**Annex 5**

## Missing Data from NHS Digital Audit April 2018

https://www.cebm.net/2017/12/transvaginal-mesh-timeline/

1. No information from GP databases. Many mesh women are stuck in the medicating for pain and UTIs trap so get no further - and are not in hospital statistics.

2. No information included on women treated in military hospitals.

3. Nothing about ventral mesh rectopexy as there is no hospital code specific to this procedure.

4. Audit shows 221 removals at UCLH hospital in 10 years, yet Sohier Elneil does around 160 a year on the NHS alone. We fear her removals may be put under two names Elneil and El-Neil and would request that this be checked. We would query why her removals data is showing up as so low when she is the key removal expert in the UK? This demonstrates that the data is flawed.

5. No full disclosure of private hospital information. There are 206 private hospitals in England and we know this is a popular private operation so this is a large amount of missing data.

6. No data from women presenting at A&E with chronic pain, bleeding, severe UTIs and other mesh related problems which women don't realise is mesh related.

7. Snips, trims, suture procedures, partial removals and erosions/extrusions are done in outpatients, where it is not mandatory to record, so not all women will be represented in the audit.

8. No data for neurology, rheumatology and endocrinology treatment arising from mesh injuries.

9. Data may be missing from the audit as a result of the issue of medical records having been 'destroyed' or 'lost', which STM experience shows is frequent. It should be mandatory to keep records of an implant in the body for the whole of a patient's lifetime. We have many women who go to report to the MHRA Yellow Card and their records are not available for reasons stated.

10. Obstructive GP's refusing to refer patients to surgeons or mesh removal specialists, means those women suffering will not show in HES data.

11. Nursing home patients and those with learning difficulties should be contacted as many will be unaware that their pain/problems are mesh related and will not have shown up in the audit.

Medicines & Health Regulatory Agency

Responses of institutions to NHS Digital Audit Report

10 May 2018

Professor Dame Sally C Davies FRS FMedSci

Chief Medical Officer

39 Victoria Street, 7th Floor North

London SW1H 0EU

151 Buckingham Palace Road

London SW1W 9SZ United Kingdom



Dear Dame Sally,

I am writing to respond to your request for initial views and responses to the questions you asked the

Agency relating to the publication of NHS Digital's Retrospective Review.

Firstly, I would like to take this opportunity to emphasise everyone involved in caring for and protecting patients, including the MHRA, recognise some women do develop serious complications related to these surgical procedures, and these can be very significant.

No surgery, medical intervention or medication is risk free, but many women have gained benefit from these surgical procedures, when the associated benefits and risk have been considered in the conversations between patients and their treating clinician. This is because stress urinary

incontinence and vaginal organ prolapse are part of a range of conditions, which can be significantly debilitating and lifestyle limiting. Patients who have and would benefit from these procedures should

not be forgotten, even though a small number of patients have had serious complications. These two

types of complex disease processes need to be considered separately, because the surgery for treating them is quite different and the risks and complications are also different.

The review, when added to the large body of evidence we have considered over many years (including individual adverse event reports, published studies, reports and reviews), does not justify grounds for taking regulatory action. We, and other European regulatory authorities, continue to allow the use of surgical mesh to treat the debilitating conditions of incontinence and organ prolapse when used in an appropriate treatment pathway, where the associated benefits and risk have been considered during the informed consent process.

These data in the retrospective review adds to the body of evidence. Despite the known limitations of these data, detailed below, it generally shows the rate of reoperations to be in the range 0.1 – 1 percent. This is similar or lower than figures detailed in other recent studies given below. However, these are not a rate of complications (reoperations do not necessarily mean complications) and other studies have also considered other end points which have different strengths and weaknesses in attempting to determine what complications occur and how frequently. All these studies show that most of these operations are not followed by reoperations or complications beyond the usual issues of recovering from surgery. (e.g., pain, discomfort, initial urinary retention).

Broadly speaking, the recommendations within the NHS England Oversight Report, the Scottish Independent Review, the recently published Welsh Task and Finish Group Report, the Northern Ireland Regulation and Quality Improvement Authority Audit and the National Institute for Health and Care Excellence's (NICE) Interventional Procedure Guidance programme supports the continued use of urogynaecological mesh provided their specified arrangements for clinical governance are in place (these vary according to the procedure being considered).

The publication of more data is a continuing process, occurring as more experience is gained into the use of, and complications associated with, these procedures. We will continue to review this evidence and act to protect the health of all patients who need treatment.

Your sincerely, Dr Ian Hudson

Dr Ian Hudson

Chief Executive Officer, MHRA

It is acknowledged that this data adds to the body of evidence, however it is important to note to answer the questions raised we are confined by the known limitations of the data. The authors have also been transparent about their assumptions and cautious in their interpretations.

The limitations of these data include:

Coding for procedures before 2017 was less granular and precise, which has been addressed following the NHS England led Report. However, even with perfect coding practices, these data are collected primarily for healthcare management and not for research.

There are questions regarding the accuracy of data entry based on the above and the potential to put procedures in inappropriate categories.

Partial or complete removal of tape/mesh is a proxy indicator of adverse outcomes. Not all partial or complete removal operations are necessarily complications and not all complications lead to reoperation. The data produced does not cover all potential complications, for example chronic pain, nor does it accurately reflect minor complications, which would reasonably be expected where outcomes are satisfactory.

There is no information on specific materials used or identification of specific devices.

There are incomplete histories of patients with no information on potential confounding factors.

There is no information about specific operations, only groups of operations are reported on, which may carry more or less risk than other operations for the same condition.

There is no information regarding complications arising from the donor site of native tissue when this was used for slings.

Patient reported outcome measures are not known.

**"What the data tells us and how it contributes to the evidence base?"**

The analyses undertaken by NHS Digital are based on what could be considered reasonable clinical assumptions and code lists. However, the analysis can only provide limited insights because of the limitations outlined above.

If, however, the data is taken at face value it would suggest the rates of reoperation are lower than the range found in previous studies. The NHS Digital Review found reoperation rates in the range 0.1 – 1 percent depending on the disease, operation and time course considered. Looking at reoperation rate only, Mahon *et al.* (2017) found reoperation rates of 0 – 5 percent, Morling *et al.* (2017) 0.5 – 3 percent and Keltie *et al.* (2017) about 5 percent.

This new data could:

Add to the confidence that the true rate of reoperations is really in the range found, because it agrees with several other published studies using a variety of methods. It is less likely that much higher rates of serious complications are being missed in the published literature.

It also suggests either for the majority of women who have had these procedures the benefits outweighed the adverse effects, or a number of women have waited for a considerable time without removal procedures being undertaken, for whatever reason. The latter would hopefully be less likely, but it is not possible from these data to discern the actual explanation based on these analyses alone.

The decrease in operation rates for stress urinary incontinence in recent years suggests either the overall operation rate was too high or it is now too low or both. The data is not sufficient to be able to comment on which if these is most likely, or what this population level interpretation means for individual patients. The population operation rate may have decreased because of decreasing need, an increase in alternative approaches to treatment or changing

clinician/patient attitudes to the procedures. However, given the prevalence of these complex disease processes, reduced clinical need is much less likely to be the driver.

**“What questions it raises, and what are the priorities for further investigation?”**

The limitations lead us to question whether it can directly lead to priorities for further investigation. An alternate view may be to consider what other data is available and propose ways to build on it to obtain an improved view of where we currently are and how to improve things in the future.

It should, however, be noted there is already data collected by NICE and this has been interpreted by them and their Interventional Procedures Advisory Committee. Their data has come from peer reviewed scientific publications and is the best available evidence. This has led to NICE guidance on a number of representative urogynaecological procedures.

Questions which could be raised for relevant stakeholders to consider are:

Is it possible to gain more useful information from this complicated data set by dedicated independent academic analysis? For example, could specialised subgroup analyses show types of operations or subgroups of patients that are at higher risk?

What is the best way to collect routine data in future to increase its usefulness? Where does the balance lie between secondary use of data collected for other purposes (e.g. using HES for safety vigilance) and dedicated data sets for each purpose? Dedicated data sets, such as registries, may be of higher quality, but take extra resources to build and maintain and lack ease of integration between systems, potentially missing information in areas that cross over, for example the putative relationship between urogynaecological mesh surgery and chronic back pain would be obscured if there were multiple separate registries.

How can the tracking of specific devices improve and what are the best procedures for later analysis? This may include cross linking a HES episode using upgraded, detailed, OPCS codes with a Unique Device Identifier (UDI). The introduction of UDI is in development and use of such labelling is in the new Medical Device regulations. Of note, the Scan4Safty programme, which will eventually be in all Trusts by 2021, will ensure all implanted devices have a barcode and are scanned at the point of entry, this data will form part of the patient records and any complications will be able to be linked back to the type of implanted devices used.

Is it possible to gain insight into the whole life course of a patient? This means understanding what happens to them when they leave hospital, which would include greater understanding of the natural history of these complex diseases processes.

Can routine data be used to determine the actual, or optimal, rate of an operation in a population and indicate the maximum benefit for the most patients?

What effect does population level intervention have on individual care? This needs to be answered, because the population rate of operations has fallen, and we need to understand the causes of this. It could be because some unnecessary operations have stopped being undertaken or both unnecessary and necessary operations have decreased, or because the operations which really need to be undertaken have reduced.

What would similar data from care in the independent sector show? There is no reason to believe it is of lesser quality, but there may be an element of supplier induced care, but this is unknown at present?

Nevertheless, we realise it is important to gain a better understanding of the actual number of women who have experienced complications and to better understand how many women have benefitted from these procedures. So possible steps for further investigation by relevant stakeholders include:

Development of a prospective registry get a more complete picture of good and poor outcomes of all urogynaecological procedures including complications and when they occur. MHRA support this idea and already participate in work led by Department of Health and Social Care to gain more information and long-term data as outlined in recommendation 4 in the NHS England Report. We recommend a similar scope and aims to that in the National Joint Registry.

Consider changes to the way HES data is collected, what data is collected (which specific devices if any are implanted, chronic pain and patient reported outcomes measures (PROM) information) and how it is used. This would perhaps allow all procedures and outcome information to be gathered over time to gain a better understanding of all procedures undertaken (not just urogynaecology) whether they use devices or not.

MHRA aim to:

Continue to collaborate with EU and non-EU regulators to gather and share information.

Convene an independent Expert Advisory Group to examine new evidence and provide strategic advice on the actions and decisions MHRA takes with particular reference to guidance to clinicians on the introduction of new devices.

Continue to provide input to the DHSC Scan4Safety programme and to encourage the use of unique device identifiers (UDI) in long term initiatives to track devices in individual patients to gain a more complete picture of mesh complications and when they occur with the aim of improving future patient safety monitoring.

## BSUG Comments on NHS digital report

### Question 1 - What the data tells us and how it contributes to the evidence base

- Gives us overall number of procedures for stress urinary incontinence (SUI) and prolapse surgery of every type. All data are presented as Total numbers from 2008 to 2017 and annual break down by HES calendar years (1st April to 31st March).

- Informs us of the number of mesh procedures being done for SUI and prolapse.

- Informs us of the number of mesh removals within 30 days of the initial surgery and in the long term.

- Informs us of the number of readmissions for women who undergo these procedures.

- Data suggests there has been an overall reduction in the number of SUI and prolapse operations being undertaken with a halving of SUI surgery and a 32% overall reduction of all urogynaecology procedures being undertaken in hospital where HES data is collected.

- There has been an increase in the number of non-mesh procedures for SUI but the number of mesh used for prolapse has remained relatively constant. This is in spite of the fact that the use of vaginal mesh has almost completely ceased. We can extrapolate that vaginal mesh has been replaced with abdominal mesh.

- Data relating to mesh removal for Prolapse are reassuring with 0 removals within 30 days of insertion since 2012 and overall decreasing numbers annually. This is likely because very few vaginal meshes are being inserted.

- Data relating to removal of incontinence meshes are reassuring with less than 1% being removed within30 days of insertion.

- The data does not greatly add to the evidence as more comprehensive studies using HES data have previously been published. Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of 92,246 women. Keltie K, Elneil S, Monga A, Patrick H, Powell J, Campbell B, Sims AJ. Sci Rep. 2017 Sep 20;7(1):12015. doi: 10.1038/s41598-017-11821-w.

**Question 2 - What questions does the data raise and what are the priorities for further investigation?**

- The main priority identified form this study is to set up a mandatory prospective database to record all mesh and non mesh complications.

- Has there been a reduction in procedures for SUI and prolapse? This seems accurate for SUI as it is reflected in the BSUG database but does not seem accurate for prolapse surgery. Is the reduction because
  -the patients with a problem in the population have been treated
  -patients are suffering in silence and not coming forward
  -patients are unable to access the services
  -patients are anxious about the mesh situation
  -patients are choosing to access non-surgical options
  -patients are being operated on in the private sector and therefore are not being recorded on the HES data
  - GPs are not referring to secondary care

- What is the level of activity for these procedures being undertaken in the private sector? NHS work has been contracted out to the private sector since around 2008. It is possible that many operations are performed under NHS contracts in the private sector and are not recorded on HES.

- The data does not give us rates of individual complications arising during surgery, success and failure rates, or long term outcome data on any of the procedures. This is an integral component of both SUI and Prolapse surgery (NICE recommendation).

- The reasons for readmission is not recorded. For example some hospitals have a policy of sending patients home with a catheter after an SUI procedure and bringing them back for a TWOC a few days later. This would count as a readmission but is actually part of routine care for that episode.

- It is unclear which of the SUI tapes were more problematic. The Scottish report found the Obturator tapes (TOT/TVT-O) to have association with more groin pain, greater removals and lower success when compared to the Retropubic tapes (TVT). This distinction has not been made in this report.

- To analyse Orthopaedic and other OPD admissions confuses the picture. The media have interpreted this as being a direct causal link to the use of the mesh when in actual fact there is no such association and therefore is counterproductive (Note high rate of referral for Non-Mesh procedures to orthopaedic services).

- The data suggests that only 133 NON mesh tape procedures were done for SUI in 2016 -2017. This is inconsistent with the data on the BSUG database which suggests Bladder neck injections have seen an eight fold rise in numbers, Colposuspensions (combined open and laparoscopic) have had a five-fold increase and Fascial slings have increased 4 times. How accurate is this data and have they been adequately coded in HES? This raises questions regarding the integrity of the whole dataset.

- Outcome data are required for all mesh and Non Mesh procedures for urinary incontinence and prolapse. This can be achieved by mandating the BSUG database.

- In the section on Mesh for prolapse no distinction is made between mesh inserted vaginally or abdominally. This is a huge limitation as the media have interpreted this as continuation of the vaginal mesh procedures when in actual fact there has been a drop off (less than 1% for primary prolapse according to the latest National Prolapse Survey) with a corresponding rise in abdominal mesh. The abdominal mesh is a procedure which has been in clinical practice since 1992 when the first synthetic meshes were used abdominally and found to be effective with a low rate of removal.

- The data does not inform us how many of the mesh complications have been reported to MHRA.

NHS England

Skipton House

80, London Road
London
SE1 6LH

Professor Dame Sally Davies

Chief Medical Officer

Department of Health and Social Care

39 Victoria Street

7th Floor

London

SW1H OEU

14 May 2018

Dear Sally,

**Retrospective Review of Surgery for Urogynaecological Prolapse and Stress Urinary Incontinence using Tape or Mesh**

Thank you for your letter of the 25 April regarding the NHS Digital publication released on 17 April 2018, reviewing Hospital Episode Statistics (HES) data on surgery for urogynaecological prolapse and stress incontinence using tape or mesh.

As you will be aware NHS England, through Keith Willett, have led for DHSC the investigatory and response work on this issue, and chaired the Mesh Working Group and Oversight Group from 2013. The following reflects that experience.

As requested, we have attached as Annex A an NHSE internal summary of the main limitations and findings, including data from the main review and from the

comparator code samples from outside the Clinical Classification Service list that were published alongside it.

Limitations of this HES data review include the exclusion of patients having procedures outside England or private procedures in non-NHS facilities, the potential to count one woman as multiple patients under certain circumstances, the inability to distinguish partial from

complete implant removal earlier in the study period, and the inability to identify the indication for outpatient attendances, or the severity of conditions. It does not include primary care data.

Key findings include:

A decrease in the number of mesh and tape insertion procedures over the study period.

The 'best working estimates' of removal rates within the 9-year study period are 3.57% for tape for SUI and 1.32% for mesh for prolapse. The removal

rates are generally lower for more recent procedures

Outpatient attendance rates in the selected specialities were greater than in the general population for all study groups: tape for SUI, non-tape for SUI, mesh for prolapse and non-mesh for prolapse.

Our recommendations for further investigation are set out below.

**Recommendation 1: Independent review of data**

Given the complexity of the data and the need for clinical context, we recommend

the commissioning of an independent academic body to analyse the data used in the review, incorporating urogynaecological expertise to develop hypotheses in its interpretation.

This may include simple estimates of implant survival rates and the comparative risks of requiring hospital outpatient care, the potential reasons behind increased outpatient attendance rates, differences between hospitals in insertion and removal rates, annual variations in practice, issues in determining the severity of complications, and inferences about private patient outcomes.

**Recommendation 2: Qualitative research**

It is unclear whether the increased rates of outpatient appointments observed in all 4 groups were related to complications of surgery, unresolved symptoms of prolapse

or SUI, or unrelated. Additionally, it is unclear whether they represent a minority of women with a large number of attendances each, or an increased number of attendances across a higher proportion of women.

The data do not allow an assessment of whether the tape vs non-tape and mesh vs non-mesh groups are comparable – there may be differences in the severity of the women's conditions preceding surgery (inclusion bias), and it is unclear what factors may have underlain the decision as to whether tape/mesh or non-tape/mesh surgery was performed (intervention bias). Similarly the current audit does not provide information on the onset, longevity or severity of symptoms arising after surgery.

These issues would be better explored by qualitative research (semi-structured interviews) into the experiences of patients of their care including consent, information, treatment, outcome and complications, and the personal, family, social and employment impact. Candidate participants could be recruited from each of the

4 groups (tape and non-tape for SUI, mesh and non-mesh for prolapse) including those who had removal surgery or for whom there were recorded multiple relevant out-patient treatment function codes, and those without apparent complications.

**Recommendation 3: Prospective registry**

Proceed with the intended prospective national clinical audit of urogynaecological procedures for stress urinary incontinence and vaginal prolapse.

Happy to discuss further,

Yours sincerely,

**Professor Steve Powis**

**National Medical Director England**

**Professor Keith Willett**

**Medical Director for Acute Care & NHS Emergency Preparedness**

**NHS England**

**Response of NHS England**

## Summary of Results for NHSD Retrospective Review of Urogynaecological Mesh Procedures

For reference purposes

### Introduction

1. This review used English Hospital Episode Statistics data to generate the first patient-level linked dataset to allow a 9-year period 'life course' analysis of removal surgery and relevant outpatient attendances for women after urogynaecological procedures for stress urinary incontinence (SUI) and vaginal prolapse. This comprised a group of women who had a tape insertion for SUI and a comparison group of women who had a non-tape procedure for SUI, and a group of women who had a mesh insertion for prolapse and a comparison group of women who had a non-mesh procedure for prolapse. It includes only activity

   from April 2008 to March 2017, for NHS-funded procedures or private procedures performed in NHS hospitals, in England. It also considers the use of those outpatient clinics by women of a similar age in the wider English population. It does not include visits to General Practice for which there is no comparable complete dataset.

2. The main analysis included OPCS operating procedure codes identified by NHS Digital's Clinical Classifications Service. In that, the main 'non-tape for SUI' group contained only one procedure – the suprapubic sling procedure, which is used to code the insertion of a rectus sheath sling made from the patient's own tissue (rather than synthetic mesh). From the academic literature and from expert urogynaecological consultation, some additional relevant non-tape and non-mesh procedure codes were identified and analysed in the same way to enhance comparison. These were not included in the main report, but were published in a separate file alongside it, linked as 'Management Information –

   Statistics of Additional Urogynaecological Codes used in Previous Analyses', and are referred to below in this summary as 'additional codes'.

3. HES data are not collected with the aim of identifying specific patients, but patient linkages can be made (by Direction of the Secretary of State) using ‘patient keys’ during data processing. This data linkage introduces a number of limitations to how the data can be used; these are described in the report and the accompanying ‘Statement of Clinical Assumptions’. For example, in certain circumstances an individual patient might be counted more than once if she had

multiple procedures in different hospital episodes in the same year. It also groups data by the NHS's reporting years, not the 12 months following any specific procedure date.

4. Additionally, OPCS codes for removal did not, for the early part of the study period, distinguish between complete and partial mesh removal, and so removal rates could be overestimated by not distinguishing multiple partial removal procedures in one woman from several single removal procedures in different women.

5. Removal activity is also recorded in groups who had a non-tape or non-mesh procedure (who would in principal not have tape or mesh to remove). This is likely to be explained by women who have had multiple procedures in whom tape or mesh was inserted before March 2008, treated outside of England, or privately funded surgery which was not performed in NHS facilities.

6. The report quotes the *total numbers of patients having removal procedures* within the audit period. In 2008/9, 580 removals were identified of which 434 had *no initial procedure* within the audit period. In 2016/17, 502 removals were identified of which only 157 had no initial procedure within the audit period. These again are expected to represent insertions pre-2008, treated outside of England or privately funded surgery which was not performed in NHS facilities. It is inappropriate to include these in the calculation of any cumulative mesh removal count or rate as the insertion population from which they are drawn (the denominator) is not known. This retrospective audit therefore is **primarily focussed on the population of women from 2008/9 to 2016/17 for which all the individually linked coded information is available** and represents as complete a hospital treatment history as possible and the incidence and rate of further treatments in each subsequent reporting year after their primary procedure.

7. In addition to their surgical procedures, the review examines rates of outpatient attendances assigned certain selected *treatment function codes* (which are related to the hospital specialty visited). These codes were identified as those to which patients with symptoms relevant to mesh/SUI/prolapse surgery complications were likely to have been referred. They include the specialties of Colorectal Surgery, Gynaecology, Pain Management, Rehabilitation (including Physiotherapy and Occupational Therapy), Trauma and Orthopaedics (relevant

   to back and groin symptoms), Urology, and a combined group of other potentially relevant small specialties. To note 'Trauma' in this context is not psychological injury but is just part of the name that refers to the specialty of Orthopaedic Surgery which also deals with the unrelated treatment of broken bones.

8. Comparison was made with outpatient attendance rates for the wider general population of women, grouped by age for the year 2016/17. The attendance rates cannot distinguish between multiple attendances for one woman, or many women having a single attendance each.

9. The collected data did not include in a useable way the clinical reason for which the patient had been to that outpatient clinic – it could have been for i) reasons related to a complication of their surgical treatment (mesh or non-mesh), ii) unresolved ongoing symptoms of SUI or prolapse, or iii) another medical problem wholly unrelated to SUI/prolapse or their treatments. Some attendances might also be routine planned follow-ups from the primary surgery - the first outpatient appointment at Gynaecology or Urology within 3 months of surgery was excluded for this reason, but those thereafter were included.

**Stress Urinary Incontinence – Summary of findings**

**Insertion / Initial Procedures**

*Tape for SUI (in main analysis)*

10. 100,516 tape insertion procedures for SUI were carried out during the study period between 2008 and 2017.

11. The annual rate of such surgery has declined from 13,990 in 2008/9 to 7,245 in 2017/18, a 48% reduction in activity.

*Suprapubic Sling Procedure - non-tape for SUI (in main analysis)*

12. The suprapubic sling procedure was carried out at a rate of between 113 and 173 procedures per year. This was the 'non-tape for SUI' procedure used in the analysis.

*Non-tape (additional codes)*

13. A further 9,230 non-tape procedures were identified during the study period from the group of additional procedures for SUI, outside the main analysis.

14. The yearly rate initially fell year on year from 1,379 procedures in 2008/9 to 908 procedures in 2014-15, before rising again to 1,585 procedures in 2016/17.

**Removal Procedures**

15. The proportion of patients having a removal procedure within 30 days of a tape insertion procedure for SUI ranged from 1.2 to 1.7 patients per 1000 (0.12-0.17%).

16. The peak of removal activity occurs in the reporting year after the year in which the procedure was performed.

16.1. The highest individual rate of removal in the year after insertion was for the 2012/13 insertion group, for which the rate of removal in 2013/14 was 13.1 per 1000 insertions (1.31%).

16.2. The lowest individual rate of removal in the year after insertion was for the 2015-16 insertion group, for which the rate of removal in 2016/17 was 7.3 per 1000 insertions (0.73%).

16.3. Overall, the number of removal procedures per year has decreased over the study period.

17. This review methodology does not allow a formal description of the cumulative rate of removal, as although individual patient data are linked it counts removal procedures not patients, and historical coding methods did not distinguish between full and partial removal.

18. With this caveat, a *best working estimate* of the cumulative removal rate within the 9 years can be made by summing the average removal rates from the reporting year 1 post insertion, plus the reporting year 2 post insertion etc. for each insertion year group. That generates an estimated cumulative removal rate during the 9-year study period of 3.57% for tape procedures for SUI.

19. For comparison, the same calculation for the group of additional non-tape code procedures generates a rate of 2.1%. *Removal in the non-tape group may imply that those patients had had mesh or tape insertion outside England, prior to 2008, or privately.*

20. The 2008/9 tape insertion group had a cumulative removal rate of 3.92% over 9 years.

21. In the context of 113-173 suprapubic sling procedures being performed per year,

    0-7 removal procedures per year have taken place. The peaks of 6 and 7 cases were in 2008/9 and 2009/10, with a decline thereafter.

**Outpatient Attendances**

22. The tables below indicate the comparative use of outpatients by the general population, the tape, the non-tape sling and additional non-tape procedure patient groups.

23. Attendance rates were generally higher in the reporting years after surgery than in the reporting year in which the surgery was performed. *To reflect this, outpatient figures quoted below exclude those in the same reporting period as the surgical procedure occurred*.

24. Rates of outpatient attendances in 2016/17 for all the selected outpatient groups are higher in women who had any type of procedure (tape or non-tape), at least one reporting year before, than they are for women in the general population.

*Outpatient attendances in 2016/17, for procedures pre-2015/16 (i.e. at least one reporting year previously), compared with female population baselines by age for the same year. Quoted ranges represent results analysed by year of initial procedure.*

*Baselines are expressed per 100 women; post-procedure counts are per 100 procedures.*

| *All values are for reporting year*<br>*2016/17* | **General Population Baseline**<br>**41-59 year olds** | **General Population Baseline**<br>**>60year olds** | **Tape procedures** ( >1year previously) | **Non-tape Suprapubic sling procedure** (>1 year previously) | **Additional non-tape code procedures** (>1year previously) |
|---|---|---|---|---|---|
| Colorectal | 12 | 16 | 23-25 | 24-41 | 32-43 |
| Gynae | 13 | 9 | 24-65 | 16-63 | 27-107 |
| Pain | 4 | 3 | 8-10 | 8-21 | 9-16 |
| Rehab | 17 | 20 | 32-37 | 9-60 | 28-51 |
| Orthopaedic | 19 | 29 | 39-44 | 27-75 | 43-62 |
| Urology | 3 | 5 | 12-18 | 26-110 | 33-62 |
| Other | 34 | 45 | 52-56 | 53-98 | 70-103 |

## Initial Procedures

*Mesh (in main analysis)*

25. A total of 27,016 patients had mesh insertion procedures for urogynaecological prolapse during the 9-year study period.

26. The number of mesh insertion procedures for prolapse has reduced from over 3000 procedures per year between 2008 and 2014, to 2,680 procedures in 2016/17; a reduction of 13% between the first and last years of the study period.

*Non-mesh (in main analysis)*

27. 71,350 patients in total had a reported non-mesh procedure for urogynaecological prolapse during the study period.

28. The number of non-mesh procedures for prolapse from groups in the main analysis reduced by 12% between the first and last years of the study period, from 8,338 in 2008/9 to 7,334 in 2016/17.

*Non-mesh (additional codes)*

29. An additional 83,697 non-mesh procedures were identified using these codes.

30. 8,794 were performed in 2008/9 and 8,833 in 2016/17. The number of procedures peaked at 10,488 in 2013-14

**Removals**

31. Three patients in total had a removal procedure within 30 days of a mesh insertion.

32. The peak occurrence of mesh removals was usually in the reporting year directly after the insertion year

33. Removal rates have been lower for women having mesh insertions later in the study period. For example, the removal rate during the year after insertion reduced from 3.9 per 1000 for insertion in 2008/9 (removal in 2009/10), to 1.8 per

    1000 for insertion in 2015/16 (removal in 2016/17).

34. The highest annual removal rate was 5.1 per 1000 insertions, 0.51% (for insertions in 2010/11, removed in 2011/12)

35. As previously stated in the SUI section, this methodology does not allow a formal quantification of the cumulative rate of removal.

36. With the same caveats as described for tape removals above, the *best working estimate* of cumulative removal rate via the same method is 1.32% for mesh procedures for prolapse over the 9 years. This is a lower incidence of removal

than has been quoted in other work.

37. For further comparison, the same calculation for the group of additional non- mesh code procedures generates a rate of 0.7%. *Removal in the non-mesh groups may imply that those patients had had mesh prior to 2008, insertion outside of England, or privately in a non-NHS hospital.*

38.The 2008/9 mesh insertion group had a cumulative removal rate of 1.74% over 9 years.

**Outpatient Attendances**

39.Outpatient attendance rates for all specialties increase in the reporting year after a mesh or non-mesh procedure.

40.Outpatient attendance rates in 2016/17 were again higher in the studied specialty group categories for women more than one reporting year after any prolapse surgery, with or without mesh, than they are in the general female population.

*Outpatient attendances in 2016/17, for procedures pre-2015/16 (i.e. at least one reporting year previously) compared with population baselines by age for the same year.*

*Baselines are expressed per 100 women; post-procedure counts are per 100 procedures.*

| *All values are for the reporting year 2016/17* | **General Population Baseline 41-59 yr old** | **General Population Baseline >60yr old** | **Mesh procedure** ( >1year previously) | **Non-mesh procedure** ( >1year previously) | **Additional non-mesh code procedures** ( >1year previously) |
|---|---|---|---|---|---|
| Colorectal | 12 | 16 | 27-39 | 22-27 | 27-33 |
| Gynae | 13 | 9 | 23-79 | 16-65 | 22-72 |
| Pain | 4 | 3 | 7-9 | 5-8 | 7-10 |
| Rehab | 17 | 20 | 28-43 | 25-35 | 32-38 |
| Orthopaedic | 19 | 29 | 38-47 | 35-43 | 39-46 |
| Urology | 3 | 5 | 9-11 | 7-9 | 9-12 |
| Other | 34 | 45 | 50-56 | 46-50 | 50-56 |

**Response by Royal College of General Practitioners**

**Retrospective Review of Surgery for Urogynaecological Prolapse and SUI using Tape or Mesh, England - April 2008 to March 2017**[1]

In responding to above audit, the Department of Health and Social Care requests you use the template below. Templates submitted by organisations before **noon Monday 14th May** will be shared with other respondents.

**Organisation responding**…*Royal College of General Practitioners.*

**Question 1 - What the data tells us and how it contributes to the evidence base**

Thank you for asking for comment by RCGP on this important subject. The data is useful as it provides information from Hospital Episode Statistics on the numbers and types of patients who had surgery for urogenital prolapse. It therefore gives a picture from a hospital setting of the numbers of procedures.

**Question 2 - What questions does the data raise and what are the priorities for further investigation?**

By definition, the data is extracted from Hospital Episode Statistics and thus does not include any information from primary care where patients will have consulted both prior to surgery and afterwards. It is therefore not possible to provide a full picture of the impacts upon patients.

Given the very high levels of computerisation of general practice within the United Kingdom and especially in England, it would be helpful to also look at primary care data and especially if further work is being undertaken to investigate the degree of clinical impact the surgery had on women. We would expect that the vast majority of general practices would have coded (with the EMIS GP computer system using Read Code V2 Release v137) within the "genital prolapse" coding hierarchy (K51). We observe that there are codes used once a woman has had surgery. For example "Other repair of vaginal Prolapse" 7D18. There also some specific codes for mesh repair operation and specifically "Repair of vault of vagina with mesh using vaginal approach". This has a code of 7D197 in EMIS. We do not know how often this code has been utilised but would anticipate that it would be less commonly used so that if primary care data was to be utilised, there would likely need to be further work to confirm the type of operation that a patient had

received.

Dependent upon the focus of any question, our recommendation is that HES data be supplemented with information from primary care.

[1] https://www.gov.uk/government/statistics/retrospective-review-of-surgery-for-vaginal-prolapse-and-stress- urinary-incontinence-using-tape-or-mesh-england-april-2008-march-2017

# BAUS Statement on:

Retrospective Review of surgery for Urogynaecological Prolapse and Stress Urinary Incontinence using Tape or Mesh May 2018

Members of the British Association of Urological Surgeons are rarely involved in mesh insertion for prolapse procedures therefore we have replied with regards to the use of mesh or tape for stress urinary incontinence procedures only. BAUS welcomes this retrospective review but appreciates the limits of the information it can provide.

**What the data tells us and how it contributes to the evidence base**

Between 2008/09 to 2016/17 100,516 patients had a reported tape insertion for stress urinary incontinence. There was a significant reduction of 48% in the number of women having these procedures between 08/09 and 16/17. Although there is no information as to why the reduction occurred it is unlikely that this was due to a reduction in the incidence of stress incontinence. Therefore, it is reasonable to assume the reduction is patient or surgeon driven (or both). It is also evident that the reduction in tape procedures is not accompanied by a reciprocal increase in non-tape procedures. There is a significantly smaller number of non-tape procedures for stress incontinence recorded over the 9-year period. So instead of an increase in non-tape procedures to compensate for the drop in tape procedures there has in fact been a decrease of 6%. This suggests that many women who would previously have undergone surgery for stress incontinence have not done so. We are concerned at this dramatic reduction in the uptake of stress incontinence surgery and feel that these data reflect an increasing number of women who are remaining affected by this extremely distressing condition.

The removal rate for tapes has decreased over the time period, from 10.2 (per 1000) to 7.3, although there is no information as to the reasons patients underwent tape removal so it is difficult to make any interpretations from these data. The overall rate of tape removals is low and we can

use these data as reference for patient counselling in the future. We are mindful that this may be an underestimate of tape removal rates due to well-documented deficiencies in coding. There is an increase in outpatient attendances with a Trauma and Orthopaedic Treatment Function from 34 per

100 in 2009/10 to 44 per 100 in 2016/17. BAUS has assumed this has captured patients attending emergency settings for any reason and is not specific for mesh or indeed urinary issues and does not capture attendances at GP surgeries, urology clinics, pain clinics or indeed the many potential areas where women with problems after stress incontinence surgery may present. There is a decrease in the same figure for patients with non-tape procedures (44 to 29). It is impossible to make any firm conclusions from these non-specific measurements.

**What questions it raises and what are the priorities for further investigation**

BAUS feels some clarification regarding the decrease in surgery for stress incontinence and what impact this is having on women is much needed. We are concerned that the publicity surrounding mesh procedures has prevented women from seeking help for stress urinary incontinence.

Although the review has captured the surgical removal rate which has in fact decreased from 10.2 (per 1000) to 7.3 it has not captured the other reported complications such as pain and mobility problems, sexual symptoms or chronic infections. For women to make an informed choice about undergoing a surgical procedure for stress incontinence and decide what procedure they should have these data are essential.

BAUS would also like to reference the important publication published online September 2017

'Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of

92246 women' Keltie K et al. Nature Scientific Reports 7: *12015* DOI:10.1038/s41598-017-11821-w. They quoted a periprocedural and 30 day complication of 2.4% for TVT and 1.7% for TOT. The complication rate within 5 years was quoted at around 10% but unfortunately the type of complications have not been reported in detail. With all of these data available BAUS feels they should be accessed and further interrogated to provide better detail and understanding of the complications recorded. This paper also quoted a 94% re-admission-free and re-operation-free rate following sub-urethral tape insertion for stress incontinence which highlights the conflicting information currently available to patients and surgeons alike. There is an urgent need for these issues to be clarified as the incidence of surgery for stress incontinence has fallen so sharply and we can only conclude that women are choosing to put up with what is an embarrassing and disabling set of symptoms.

BAUS is committed to providing the best care for women with stress incontinence and has updated all the relevant information leaflets on their website which are now available to all providing information for all of the different stress incontinence procedures. BAUS will continue to update them as new evidence emerges. There is also a specific information document summarising all the treatment options for stress incontinence to allow women to make a fully informed choice.

**Annex 6**

## Transvaginal Mesh Implant Detailed Timeline of Events

2003 Gynecare TVT introduced via an Oxford John Radcliffe audit by Simon Jackson & Natalia Price and an HTA authored by Cathryn Glazener. The HRA notes complications are over 8% for some types of complications & recommends a mesh surveillance system & audits & that women should be warned of risks, but also notes that mesh appears to be cheaper than standard repair, if it doesn't require further high rates of intervention.

2003 NICE produces a summary appraisal of the HTA for Gynecare TVT and the Oxford audit, which states Linda Cardozo is the advising exper . This NICE TVT guidance is supported by the Patient Groups: Incontact & Continence Foundation. Linda Cardozo & Christopher Chapple are Directors/Trustees of One or both organisations, at that time.

2005-6 . NICE chasing doctors for audits on mesh

2008 FDA 1st warning on mesh safety

BSUG Database created & suggested as database for Trials

Canadian guideline review panel reviews the Gynecare TVT 2003 NICE appraisal, and noted that some of the included studies have been retracted from medical journals due to trials failing ethics or other standards

2008-9 The Prospect Trial starts recruiting. There are more people in the trial then they report results for, ie over 1,000 but they only give results for about 350 (what happened to the others? They said up to 90% of women in the prolapse trial had urinary incontinence? and many had mesh already for SUI? They repaired or removed mesh in the trials and sometimes inserted new mesh). STM are concerned that trial protocols were not followed.

2008-9 RCOG shocked by 30 day readmissions to hospital after TVT & TOT, starts preparing a safety in gynaecology report in 2008-9.

2008-9 NICE & HQIP still chasing BSUG and doctors generally for mesh treatments audits

Birmingham /Sandwell NHS trust Dr Arun trials after the trust suspends the use of mesh

2009 Exponential growth in MHRA reports, coincidentally, when the Prospect trial starts in full swing . Reports go from almost zero to 30 per year. Most reports from women & manufacturers. Women, doctors and hospital report devices (if known). Trials are supposed to but probably only reports deaths. Drs/HCPs have anonymous reporting, they do not have to give their name or hospital details, just the product & the manufacturer. But most do not even do this.

2011-12 Terminology of mesh produced, categorising mesh erosion/expulsion & haematomas (blood clots) etc as a symptomatic. The new standard for trial reporting.

2011 FDA 2nd warning on Mesh

2011-12 York Mesh enquiry review. State mesh is safe.

2012 May. RCOG publishes the Safety in Gynaecology report on mesh surgery

2012-14 TVT mum mesh group still trying to get the MHRA to monitor mesh, and meets the MHRA to explain the full range of complications/disabilities occuring, not just incontinence.

TVT Mum ask for more trial funding to extend the trial by 5 yrs.

NICE still chasing doctors, & BSUG for Mesh audits, but they never happened

They then start VUE & Sims Trials around 2013 -14 (when Prospect ends).

2014 Scotland suspends transvaginal mesh

2014 MHRA issues Patient Safety alert that doctors are not reporting the manufacturer & device names on devices generally, for NHS products in 60-80% of reports.

MHRA inform all hospitals, as of 2014, they must all have Medical Device Safety officers to oversee safety of devices & report centrally on any issues, including re recalls, encouraging HCPs & the MDSOs to report device issues.

Mesh manufacturers start losing big trials. Some go out of business. UK oblivious, no product liability trials whatsoever, just piecemeal clinical negligence trials. But pro-mesh experts may have advised lawyers that it is not the mesh, it is surgical skills that is the problem.

2014 European Commission SCENHIR enquiry into mesh, says it is waiting on Prospects trial results (still not published, despite using BSUG's new database)

VUE is a mesh kit trial. Repairing people who already have failed mesh in  - this was curious timing, along with the end of the PROSPECT trial. Are they repairing Prospect mesh failures?

2014 MHRA published summary of risks & benefits of mesh. They say they are waiting on the results of SIMS, Prospect trials but in the interim based on the evidence they reviewed mesh as safe.

2015 NHS England mesh enquiry says mesh is safe. Lots of people then resign from it enquiry. They say they are waiting on the results of SIMS, Prospect trials but the interim based on the evidence they reviewed and state mesh is safe

Sling The Mesh support group created & grows exponentially

Around this time the MHRA is getting lots of criticism about mesh, breast implants, hip implants, they then call out the doctors for unskilled surgery & failing to report devices, so the system cannot work. MHRA admit they do not have the clinical expertise to really understand the issue, but doctors' societies need to manage their doctors better. MHRA do not have resources to review every product coming into the UK properly, they just check if when the product is introduced, that all the paperwork is in order. They are too underfunded to do more than that and that Government needs to give them more.

Database registries again suggested. BSUG again thinks it is the one the Government should "fund" despite the fact they still cannot produce a proper national audit from it; they make all decisions with manufacturer input and funding. Despite being around for at least 7 years, only about 60% of the centres registered actually put their outcomes on it, and they don't put their long term follow up on it anyway so unclear what difference it makes. Database is used in trials so why does it take 4 years for results to be published?

Lots of Trusts still avoiding complying with Audit, saying they don't do SUI procedures, when they are high mesh users, & many are accredited centres.

SCENHIR states mesh is safe, before the Prospect trial results are published

2016 SIMS sling TOT etc trial stops recruiting but still does not publish results

2016 Birmingham/Sandwell trusts recalls Mesh patients treated by Dr Arun. He continued inserting & doing Trials when they had banned it

Dec 2016 Prospect HTA result published. Results show severe complications at higher than published rates

2017 Fibroid Network, starts raising awareness of specific medical literature & the Mesh Trials, that confirms much higher numbers than enquiries have suggested & encourages other women's health groups to help raise awareness, as many women are affected

2017 April Victoria Derbyshire show raises awareness on mesh risks

2017 Class actions announced in England & Scotland

2017 July APPG Mesh Parliamentary enquiry

2017 Aug 135,000 reports of mesh harm in FDA Maude database. Over 100,000 women suing in USA,

2017 Australian Mesh enquiry

2017 Prolapse & SUI guidelines updated in UK. Mesh for POP should only be used in a research context

Feb 2018 Parliamentary debates, still no results from SIMS & VUE trials. SIMS trial now updates & says will publish results in 2020??

It is possible mesh trial participants are not audited, so is that why they are hidden from statistics?

2018 BAUS conducts audits from approx 2013-16/17. Does not clearly specify mesh treatment data & complications. But importantly they only have 3000 outcomes with an estimated 17,000 missing for other obgyn documents for that 3 year period, ie the bulk . BAUS only have

approx 2700 results with inadequate follow up and codes are confusing. But it looks like the other 80% of patients outcomes are unknown and there had been no publication of BSUG s audit. They announced that they were only going to audit 1 year 2013 instead of 3 years like Baus. That is now overdue. They have been chased by HQip auditors since at least 2013 for this audit.  Are they hiding mesh injuries behind trial data?

Patients and media highlight the mesh problem which is being ignored, triggered by enquiries and mesh injured women begin voicing their concerns publicly.

**Case study: Economic, emotional, social and physical costs of pelvic mesh injuries – an STM member's story**

I had a TVT 'tape' operation done in 2004 aged 38. I was a very fit and healthy Mum of 3 teenagers, who cycled to work and led a very active life. I shared hobbies with my Husband and friends of Mountain hiking.

In fact we did Ben Nevis, Snowdon and Sca Fell, along with all 214 Wainwrights in the Lake District along with other mountains.

I had my TVT operation on February 9th 2004 and was in Hospital for 2 days. I was told that it was a 'simple 20 minute op' that was a tape, that was like a little hammock supporting my bladder.

The only complications mentioned were that I could have my bladder damaged during the op, but that they would fix it if they did, and that I may possibly have to self catheterise for a little bit afterwards but that was it. I was never offered alternative surgery. I was told that the Consultant was a pioneer and specialist in this surgery and that he had brought it to this Country!

I felt that this was a simple and safe procedure, more so as I was only going to have spinal anaesthetic and would be awake for the procedure as they needed me to cough at one point to make sure that the tape was in the correct position.

I got into the Operating Theatre, numb from the waist down and having been given a light sedative (they would give me a shot of adrenalin to wake me up when the time came to cough) when the Consultant said that his Registrar was going to be doing my operation with him overseeing it. Was that ok? I was in a very vulnerable position and felt unable to say no. His Registrar did the surgery and I could hear him saying 'Not there' 'No No' and other things.

Once the catheter was removed I went to the toilet and found it hard to pass urine, it seemed like it was being partially blocked and it took me a lot longer to urinate. Also, I immediately got terrible urge incontinence, when I needed to go, I had to go right there and then or I had an accident. I mentioned this to the Consultant and he said 'Both of these things are normal after a TVT'. I had never been warned before surgery!

Within a year, I was going regularly to my GP with urine and vaginal infections. My GP sent me back to the Consultant, who did nothing.

I had lots of vaginal, hip, back and abdominal pains from then on, and continual infections. I started to feel unwell much of the time. I was sent to a Spinal Specialist who gave me many epidural steroid spinal injections for pain. I had many MRI's, CT's, Ultrasounds, Nerve Conduction tests, Xrays etc.

Finally, I had major Spinal Surgery - a Lumbar Disc Replacement at L5/S1 in 2012. This did not get rid of my pain, and a year later I had Facet Joint Nerve Radiofrequency Ablation to deaden the nerves in my spine.

At the same time I had ovarian cysts, scans for gall stones due to my pain, and I had a very inflamed bowel. I felt very unwell and in pain constantly. In 2012, I was referred back to gynae

as I had a rectal prolapse. The same Consultant told me that he could fix it but as I was 48 he had to warn me that it could end my sex life. I refused the surgery (I am so thankful every day that I did, as he would have used mesh.) It was ironic that it ended anyway due to the pain of the TVT!

It had been 10 years since the TVT surgery and he had told me that it would last about 10 years, and still not knowing that all of my problems were coming from the mesh, I asked him if it needed redoing yet. He mumbled very quietly that 'my tape was still ok.'

I was diagnosed with fibromyalgia, depression, I could no longer have sex with my Husband as it was too painful to have penetrative sex. It led to a strained relationship as there didn't seem to be a reason why I was in so much pain, had strange allergies, headaches and many other symptoms. It put a huge strain on my marriage. I had to cut my hours down at work (at the NHS Hospital where I had my TVT surgery.) I started there in 2002 and worked 28 hours as a Band 3 Orthopaedic Waiting List Coordinator. I had to be redeployed as a Band 2 Cardiology Receptionist at 15 hours a week. This led to a substantial loss in salary and income and massively affected my final salary Pension, through no fault of my own.

We struggled financially as my Husband is self employed.

Around 3 years ago, I became too unwell to go out of the house, except to go to work and it was taking all of my energy to manage to work 2 days, I was depressed and was given Counselling by Occupational Health at work. I was put on more and more medication just to make me able to function, but I was like a zombie because of the medication.

I no longer had my hobbies or social life or any quality of life. I was doubly incontinent so wouldn't go out for fear of accidents. I was terrified that my Husband would grow tired of this miserable, ill woman that I had become and leave me for someone who COULD make love with him. We have been together for 29 years and married for 24 and we had always had a good, healthy sex life before this. I was terrified that we would never manage to have sex again.

I was referred for Pain Management to The Walton Centre in Liverpool which costs £16,000 per person.

In April 2017, I saw a newspaper article on a Saturday about The Victoria Derbyshire Show that had been on TV that week about vaginal Mesh. I watched it on catch up. It mentioned a support/campaign group called Sling the Mesh. I promptly joined and what a lightbulb moment that was!

These women had all the same symptoms and problems as I had and the relief that I felt, finding out what was causing my problems was immense, although I was angry too as I had NEVER been told that I had mesh. I went straight to my GP on the Monday armed with information and she agreed with me that I had all of these mesh damage symptoms. I asked if she could refer me to Miss Elneil at University College Hospital in London. She said that she would have to speak to the Surgeon who did the surgery first. He said 'Mesh isn't a problem, but to refer me to a mesh removal specialist!'

I went off work sick on May 30th 2017 as I was no longer able to do my job and am still off at present - due to pain and incontinence.

I paid £250 to see Miss Elneil privately and she referred me for a translabial scan which I had in November 2017. This was with Renee Thakar in Croydon. She told me that the mesh was too

high, too tight and in totally the wrong position for a TVT, in fact she was convinced that it was a TOT.

Miss Elneil saw me again in December 2017 and listed me for surgery for 2 mesh removal operations.

I had the first in January 2018 at UCLH. This was a vaginal mesh removal, urethraplasty and vaginoplasty. I had to travel to London by train with my Husband and he had to take time off work to be with me, meaning that he had no wages as he is self employed and had to pay for a hotel to stay in. I had 4 appointments in London before surgery, and 3 afterwards, for a Consultation, pre op appt and Urodynamics then I had my second mesh removal operation in May 2018. This meant more travel, hotel and loss of wages for 4 days for my Husband at a time when I was on half pay from work.

This operation was to remove the mesh arms/anchors, scrape the mesh off my bones, a paravaginal repair, a bladder repair (where the mesh had pierced it). It had also gone into my obturator fossa and my vulval tissue. I had 22 staples in my wound. I was discharged after 4 days and had to go home by train which was a 1 hr 50 minute journey. The drive home to Cheshire could have taken 3-4 hours. I was discharged with a catheter for 3 weeks to give my damaged bladder time to heal.

I went back in June for a cystogram and Trial without catheter. I am due to be seen 3 months after my operation in London. I have already had more vaginal and bladder infections and trouble with my scar healing but I am so relieved to have the mesh removed from my body, and that it can no longer cut into my tissues/organs inside me. I do not know yet if all my pain will go or not, and what my quality of life will be but as a mesh damaged woman I implore you to put an end to this barbaric operation. I still do not know if I am going to be able to have a sex life as it has not been possible to try due to pain before the second op and as it is too early now, but I hope I am able to for the sake of our marriage.

Mesh has caused my whole life to be affected - myself, Husband, children, grandson, parents, family, friends and work colleagues. It has caused problems for so many, not just me.

It has irreversibly damaged my mental and physical health, work life, social life, hobbies, financies. It causes huge problems in our lives and the Government and NHS need to recognise this instead of labelling us all 'compensation seekers' although we should get compensation for our suffering and losses, which should be recognised. It has cost me and my husband over £2,000 so far to travel to London for appointments, hospital stays, travel, accommodation; incontinence pads £3,250 and loss of earnings £51,500, and I am shortly about to go to no pay AT ALL as I am still not fit enough to return to work.

Please listen to mesh damaged people - we want to stop others going through the hell that we have, especially as stress incontinence can be fixed with physio, Burch colposuspension or autologous slings.

The Consultants who got rewarded by the Big Pharma companies for pushing this mesh onto us knowing that it is a dangerous product should cease using it immediately!

We also want proper help and support from the Government with costs that we incur due to mesh.

My simple op has cost the NHS over £100,000 in procedures, tests, medication, operations and also incurred massive losses to me.

Not such a cheap option was it!

*Source: STM member, June 2018*

**Annex 8**

**Women's mesh complications identified by translabial ultrasound scan**

**England**: Hi the translabial scan very clearly showed the mesh had eroded , twisted and torn in 3 places it proved it was not fit for the purpose intended . I saw a consultant on the specialist removal list , who did not acknowledge the scan he said it can only be seen with a telescopic scan and my symptoms where not mesh related and would not recommend taking it out as it could cause lots of other issues. !!!

**North Wales**: In 2014 I was implanted with mesh, I had a TVTO for stress incontinence, my complications started straight away, chronic pain in my left hip/thigh area, and I was unable to pass urine unless I self catheterised. I was sent for an X-ray which didn't show anything, over the last four years I've had numerous X-rays (6 at least) MRI scans (5) MRI with dye injected, I have been sent for heat physio therapy. Non of these showed what could be the problem. I then heard about translabial scans on the Sling the Mesh Group, I enquirer about these scans when I saw (yet again) my local gynaecologist, I was told that they are not available in Wales, I pushed for referral to Manchester (one of only 2 places who do the scans) earlier this year, 4 years after my implant I had a translabial scab, it clearly showed the mesh had been put in too tight and placed incorrectly on the left side (this side I have the majority of my pain) If my local hospital had had the capability to do a translabial scan I wouldn't have had pointless MRI's and X-rays, the cost to buy the transponder would be offset by what money would have been saved.

**England**: I had my TVT for stress incontinence after 3 babies in 2004 aged 38. Last year in April 2017, I saw an article in a newspaper following The Victoria Derbyshire Show about Mesh, which I then watched. I was totally shocked. I had been in pain in my back, abdomen and pelvis for many years and had been given epidural steroid injections for many years, undergone MRIs, CT's and Ultrasound Scans. I ended up having major spinal surgery - a L5/S1 Activ Artficial Lumbar Disc Replacement in 2012. My pain never went following that and I ended up having Radiofrequency Nerve Ablation to deaden the nerves in my facet joints in 2013.

When I found out about Mesh in 2017, I asked my GP to refer me to Miss Sohier Elneil in London, which after speaking to the Surgeon who originally did my TVT (He said 'Mesh isn't a problem, but refer her to Miss Elneil') she did do.

Miss Elneil sent me to see Ms Renee Thakar at Croydon Hospital who did a translabial and transvaginal scan. I had already had anal manometry, anal ultrasound and a defecating proctogram at Wythenshaw Hospital in Manchester to see why I had faecal incontinence.

Ms Thakar said that my tape was too high and too tight and she was convinced that it was a TOT not a TVT because of its incorrect placement. She was looking in my groin for incisions as she said it was not a TVT.

Once home, I emailed my original Consultant and asked if I had a TVT or TOT. He said definitely a TVT.

The Translabial Scan and Transvaginal Scan showed that it was too high, too tight and wrongly placed.

I had my first vaginal mesh removal, urethraplasty and vaginoplasty in January 2018 and have had my second operation in May 2018 for the mesh arms/anchor removal, para vaginal repair done through an abdominal incision, and the mesh had gone into my bladder so I needed this repairing too.

The translabial scan was vital to Miss Elneil to know some of what she was facing in the surgeries, although there can be some bits that she can't see until she operates. The mesh had gone into my obturator fossa and into my vulval tissue and also had to be scraped off my bones.

I think that it is vital that ALL Mesh Centres are equipped with Translabial Scanners and people qualified to read the scans.

**Northern Ireland**: I had TVT in 2001. 2013 I was gripped with a pain which I thought was due to a prolapse. I also developed severe bowel impaction. 2013 - 2017 I had numerous internal examinations, blood tests, ultra scans, x-rays. All tests clear.Feeling so unwell & in so much pain & discomfort I cried to GP for help in August 2017. I also suggested possibility I required hip replacement due to my pain; limp & tripping. I requested a gynecologist referral as my Daughter heard on Sky news about mesh problems. (I was unaware at this stage I had mesh).

I contacted STM NI in October 2017. It was suggested to me a Translabial Scan may give me diagnosis.

I saw Gynecologist 8/11/17. She rudely told me my TVT was fine, my bladder flo change was due to my age & a Translabial Scan would not show my TVT. She & my GP refused to give me a referral for a private Translabial Scan.( despite this being of no cost to NHS).

Following emailing my symptoms to Miss S Elneil, she kindly gave me referral Miss Thaker required for my Private scan.

I travelled to Croydon & Scan immediately showed up my TVT is too high, too tight, 'c' shape & eroded into my Euretha wall.

I now await complex surgery in London by Miss Elneil Team for mesh removal.

**England**: After having a TVT fitted in 2011, a partial removal in 2012 and a full removal by Natalia Price, Oxford in 2013 I remained in chronic pain which badly affected my quality of life.

On Christmas Day 2017 I had to go to my bed in the early evening having tried to spend the Day with my family taking part in the festivities.

As a member of Sling the Mesh I mentioned this and Kath Sansom messaged me to say that she had been told by Ms Elneil that it was not possible to remove full mesh vaginally. This was the operation I'd had in 2013.

Following on from this knowledge I booked a Translabial Scan with Indira Mistry at Ultrasound Services, Kingsbury.

Whilst the scan was in progress I was able to see the screen and even my untrained eyes were able to see pieces of broken mesh in my vagina.

I then had an appointment with Ms Elneil and she agreed that there was mesh visible.

I had this mesh and the section from my pubic bone removed in the Harley Street Clinic on 8 May 2018 and most of my pain has now gone.

Please provide Translabial Scanners to all the Mesh Centres immediately. They are a vital tool to confirm the position and condition of mesh in women as you are well aware.

**England**: I did recently have a translabial scan. However previously not long after I had mesh fitted in 2006/7 I had an MRI which did show the mesh. It was how they found that it was sticking into my bladder. It was at that point I had partial removal. Then I went on to have more removed. I was told it was all removed but since that time till now I have been in horrendous pain. I was told all my mesh had been removed but I didn't believe it. In recent months the pain has been getting worse more like it used to be. So I had a translabial scan done. No other tests this showed I still had parts of mesh still in me.

**Northern Ireland**: In June 2015 after years of unexplained pain in my legs, hips and groin which was getting progressively worse as time passed I saw Kath Sansom being interviewed on sky News about her TVT mesh implant and how she had suffered excruciating pain since it had been inserted. I realised that this was potentially the reason for my own pain. I had had the TVT since 2005 but having been advised of no risks or potential complications in any shape or form I was oblivious for 10 years that this medical device had had the potential to make my life a misery. Later that year in September 2015 I saw a gynaecologist privately through my Work Health scheme at Kingsbridge Hospital in Belfast and suggested to her that the device was indeed causing me pain. She immediately disagreed and after an internal examination advised me that my TVT was indeed in the correct place and that all was good however she referred me for MRI, vaginal floor physio and also to see a spinal surgeon as she thought perhaps it was a bulging disc at the bottom of my spine that could be to blame. In 2013 I had already had had X-rays of the same area due to this pain which showed nothing untoward and the MRI had the exact same result except for my bulging disc. The vaginal floor physio could not see anything anatomically wrong with me either and the spinal surgeon ruled out any connection with my lower back. I asked to be referred to an expert removal surgeon in London. After waiting a considerable time and getting nowhere privately I was placed on an nhs list to see a consultant in Belfast. In the meantime I decided in November 2016 to travel to Croydon from Belfast and I paid £402 for a translabial scan. This scan is not available in Northern Ireland. This scan showed that my TVT was incorrectly positioned and was sitting higher up than it should be. The consultant who scrutinised my images advised that the position of the mesh and the way it was pulling on my sacrum
was causing me excruciating pain and recommended that it be removed. By the time February 2017 came my condition had worsened and although still on an nhs waiting list with no appointment in sight i could no longer live the way I was so made the decision to pay to have my mesh removed privately. After the surgery my removal surgeon commented that the TVT was siting too laterally and too close to my bladder wall. That coupled with mesh shrinkage she could see how I had been in so much pain.
I did not have cystoscopy at any time as erosion was never suspected.

If it hadn't been for the translabial scan I would never have known that the implant was harming me and I honestly believe it would have ended up in a wheelchair.

**Annex 9**

THE BRITISH PAIN SOCIETY
EXPERTISE WHERE IT MATTERS

## The British Pain Society Press Statement on suspension of mesh surgery in NHS Hospitals

## The British Pain Society offers expert support for women who have suffered chronic pain as a result of vaginal mesh surgery complications

On 10th August 2018 the Government's review of surgical mesh for vaginal organ prolapse and/or urinary stress incontinence, called for the immediate suspension of their use. This procedure is done with the aim of relieving the distress caused by prolapse or lack of bladder control, but recent complaints from the public and media reports have shown that in many cases, it can go badly wrong and cause complications including chronic vaginal pain.

Baroness Julia Cumberlege, Chair of the Review, said:

"I have been appalled at the seriousness and scale of the tragic stories we have heard from women and their families. We have heard from many women who are suffering terribly. Their bravery and dignity in speaking out is deeply moving, and their sadness, anger, pain and frustration at what has happened to them and others has been compelling."

Dr Andrew Baranowski, President of The British Pain Society and a leading anaesthetist, has extensive experience in helping women to manage pain in this condition.

With 25 years of experience running a chronic vaginal pain clinic, he is also a recognised expert in specialist techniques such as neuromodulation and is an Honorary Senior Lecturer in pain medicine at University College Hospital. Dr Baranowski says:

"Put simply, living with chronic vaginal pain is associated with a significant negative effect on mood, thoughts, behaviour, sexual and personal relations as well as employment.

“It increases the risk of depression and anxiety and is associated with increased suicidal risk as well as mortality from other conditions like cardiac problems.

“Access to pain management is a fundamental human right.”

The British Pain Society believes in the bio-psycho-social model of understanding pain and giving the best holistic treatment, based on multidisciplinary teams which are found in many British hospitals.

The most difficult cases may need highly specialised anaesthetic procedures to help them live more comfortably. Thus women who have suffered chronic vaginal pain after mesh surgery need to turn to specialists such as Dr Baranowski, who adds:

“There are probably only five specialised vaginal pain management services in England that would meet NHS specifications to provide specialist assessment and management of conditions.

“There are limited NHS resources for those that live with chronic vaginal pain. Many medics struggle to know how best to support and manage those living with it.”

Of the 99,000 patients who are recorded in Hospital Episode Statistics as having had these surgical procedures, 9.8% had a subsequent hospital admission. More will have visited their GP or other NHS services. It is not clear how many women develop severe levels of chronic pain - according to some estimates, it could be up to 40%. Research is urgently needed to fully understand the extent of this problem.

The NHS has also issued a letter to all hospital trust CEOs and medical directors on 10th August 2018, announcing the commissioning of specialised centres which ‘will provide a new multidisciplinary team management and complex vaginal mesh removal surgery for women who have complex vaginal mesh complications’.

The British Pain Society supports the careful and responsible use of vaginal mesh surgery by expert surgeons, but recommends that women should be supported by trained pain specialists at all levels from their local hospitals up to these new specialist centres.

Kath Sansom, of ‘Sling The Mesh’ campaign which represents over 6000 women affected adversely by these complications, said:

"We are incredibly grateful for the support from the British Pain Society who are taking steps to put proper pathways of care into place for mesh injured women.

"A huge problem with the mesh implant story is that the pain is hidden. Nobody can see our injuries or how much we hurt, so sympathy and support is lacking.

"Many of the clinical trials only look at the fix and do not ask questions about new long term pain or problems after surgery. So to have our suffering recognised by such an important medical society is a huge step forward."

Acknowledging the psychological effects and serious societal consequences of the pain, Dr Baranowski says:

“When it does happen it is clear that the pain can be intrusive to the extent that some consider suicide.”

The British Pain Society PAIN:LESS Campaign recognises this silent suffering.

The British Pain Society has organised an educational event (Study Day) for Monday 12th November 2018 to bring together pain specialists of different disciplines, together with the all-important patient representatives, to discuss the frequency, impact and proper treatment for the women suffering this complication. The Society believes this will be the first high level education event focused on post-surgical vaginal mesh pain in Europe.

This Study Day is one of series being run by The British Pain Society on a wide range of pain conditions affecting the whole spectrum of the population.

A press release for the Study Day as well as our PAIN:LESS Campaign, which draws significant attention to those suffering from chronic pain, will be released in due course.

----------*End of statement*----------

For more information or to speak to one of our pain experts please contact Dylan Taylor on: Dylan@britishpainsociety.org or 0207 269 7843

**Background information for editors**

The British Pain Society (BPS) is the oldest and largest multidisciplinary professional organisation in the field of pain within the UK. The BPS aims to make pain visible and to treat it better and is the British Chapter of the International Association for the Study of Pain. It is a registered Charity.

Chronic pain is suffered by over a quarter of the population. It is commonly distressing and can be highly disabling. It is devastating for individuals who suffer it. Many cannot work and lose their jobs.

Treatment of pain is a fundamental human right, yet sadly there is an enormous gap between the care people require and what happens in practice. We also do not know enough about the cause and treatment of pain. Our alliance of professionals works collaboratively with patients and industry partners to advance the understanding and management of pain. We strive to reduce the suffering of people enduring daily pain. Our multidisciplinary nature is pivotal in making The British Pain Society a uniquely relevant representative body on all matters relating to pain. It aims to promote education, training, research and development in all fields of pain.

The Society is involved in all aspects of pain and its management through the work of the Council, various Committees, Special Interest Groups and Working Parties and via its publications, Annual Scientific Meeting and educational seminars.

**British Pain Society PAIN:LESS Campaign**

The British Pain Society aims to make pain visible and to treat it better. Pain is the most common reason that people attend their GP and affects 1 in 4 people. Persistent pain can be a major source of suffering for many and can present in many ways, for example after road traffic accidents, burns and war injuries. Pain also occurs with illnesses such as cancer, arthritis and back problems. Pain is not visible.

Outwardly people may look 'normal' but are left with life-long severe pain that can affect their mood, relationships with family and friends and their ability to work or relax. We strive to help these people.

**Annex 10**

Photo 1: Polypropylene mesh

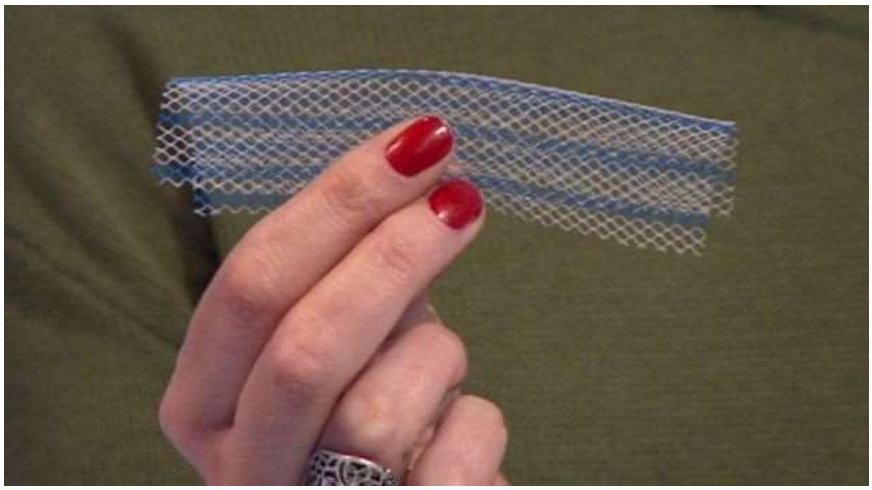


Photo 2: vaginal mesh device before implanting in the body

Photo 3: Degraded vaginal mesh after excision from the body


**Annex 11**

**Photographs of Common Mesh Complications from STM Members**

**Swollen Abdomens -** occurs daily in many women with intense pain.





**Swollen and painful feet, ankles, legs, hands –** occurs daily in some women



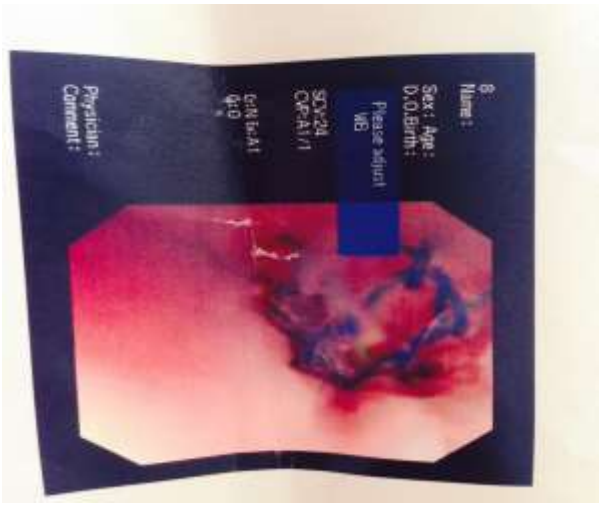
**Rashes and Itchy Skin– often** disappears after mesh removal

**Psoriasis / Eczema /Bruising** – often worsens with mesh, reduces after removal

**Mesh Migration into Bladders** – Causes pain, UTIs and bladder stones

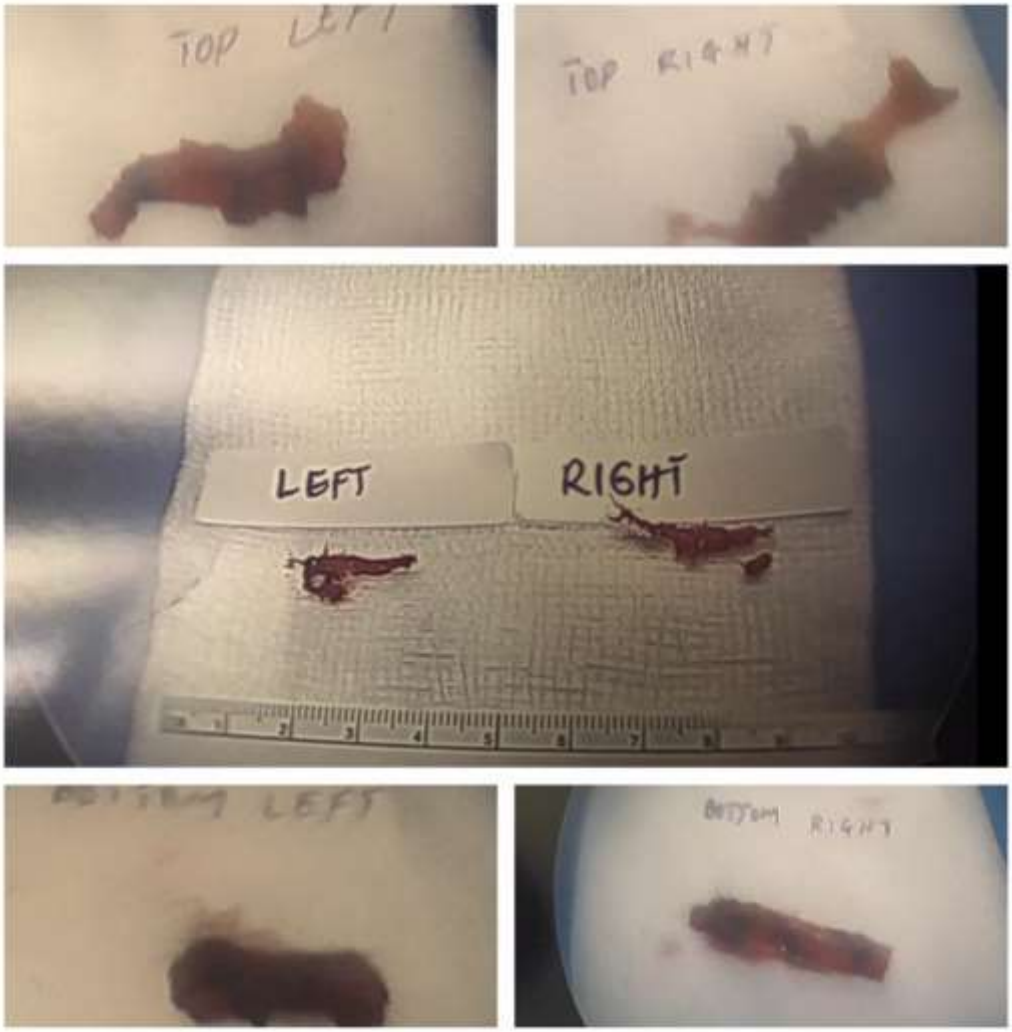
Mesh inside bladder

**Mesh Migration into Urethra** - chronic pain and UTIs, requires repair of Uretha



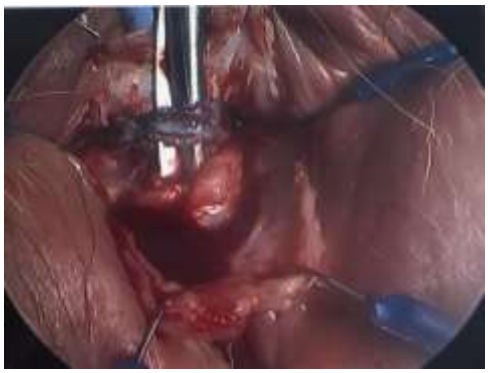

**Mesh Erosion Through Vaginal Vault** – severe chronic pain, mesh becomes hard and brittle. injures sexual partner during intercourse.

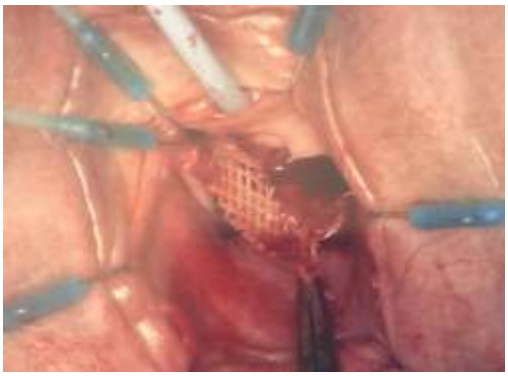
**Excised Mesh** – hard, brittle, sharp, frayed.


LEFT
RIGHT

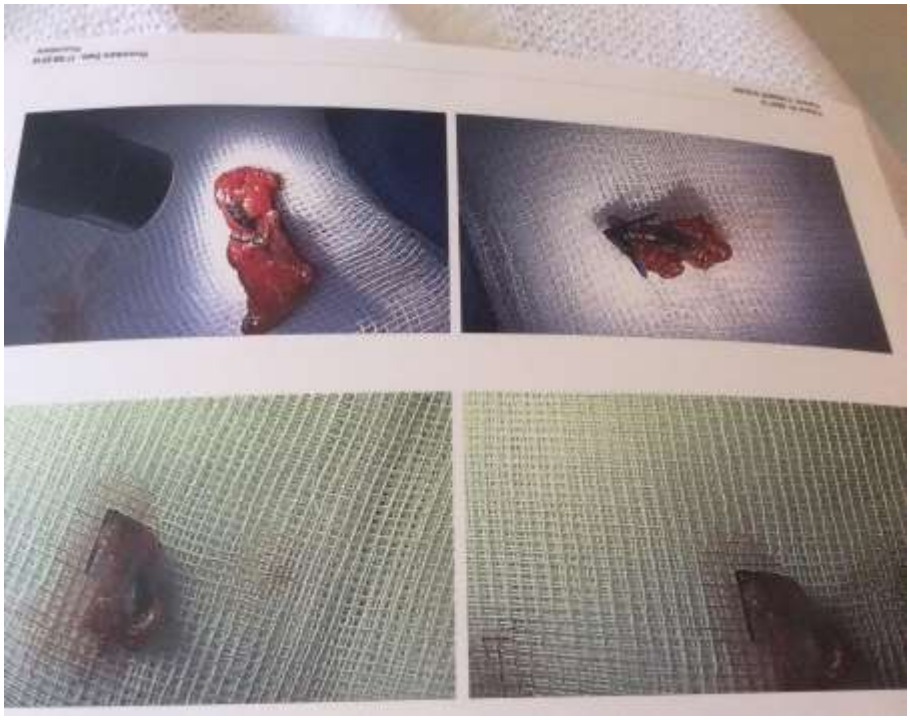

Right

**Mesh Removal Incision with 20 Staples –** Surgery is complex and carries risks of symptoms worsening or new ones occurring





**Mesh Anchors** – these have to be scraped off the pubic bone during surgery, with a risk of further nerve damage.



**Mesh Migration, folding -** has resulted in loss of bowels/stoma formation for some women

**Hair Loss and Thinning –** improves after mesh removal

**Annex 12**

**Alternatives to pelvic mesh surgeries**

STM notes that the Review Team's updated Terms of Reference states that the Review will examine "whether the scientific evidence underpinning current regulatory and clinical practice fully and properly reflects…. the risks associated with the procedure itself in comparison with the alternative available options".

Follows are a range of available alternative treatments and procedures for each type of pelvic mesh that are still within use in the UK.

1. Alternatives to mesh based procedures for stress urinary incontinence – TVT, TVT-O, TOT, SIMS

We are pleased to see that new NICE draft guidelines say conservative methods should always be tried first like physiotherapy, medication or lifestyle changes. However, this has been the official advice since 2003, yet patient experience shows us this has not been the case. Many women have been given surgery with mesh without even having had at least six months of pelvic floor physiotherapy. Many told that physiotherapy does not work. yet evidence shows up to 80% of women can be eased or cured with good pelvic floor physiotherapy.

Physiotherapy is cost effective as seen in this link: https://www.csp.org.uk/publications/physiotherapy-works-urinary-incontinence

https://www.csp.org.uk/system/files/physiotherapy_works_ui_2014.pdf

If conservative methods fail then non mesh surgeries must be the second choice option. Only once these two stages have failed should mesh be considered as the final last resort.

A. Conservative measures

i. Lifestyle changes like losing weight, reducing caffeine and alcohol intake.

ii. Physiotherapy with a pelvic floor therapist. For further comment on the availability of physiotherapy on the NHS please see section 6.4.

iii. Devices like weighted cones or bio-feedback training devices

iv. There are limited pharmacological treatments such as duloxetine.

v. Botox and urethral bulking can also be used, though efficacy may be less well established.

B. Non mesh surgery for SUI

i. Burch colposuspension known as a hitch and stitch

ii. Autologous sling where a piece of stomach muscle is used to make a native tissue sling to support the bladder neck

iii. Kelly's plication where a suture is used to help support a weak bladder neck

2. Alternatives to transabdominal mesh based procedures for vaginal/uterine prolapse (sacrocolpopexy and sacrohysteropexy)

A. Conservative methods

i. Lifestyle modification

ii. Topical oestrogen

iii. Pelvic floor muscle training

iv. Pessary management

B. Non mesh surgery alternatives to sacrocolpopexy

i. Non mesh sacrospinous fixation

ii. Colpocleisis– only for a woman who does not plan to be sexually active in the future

C. Non mesh surgery alternatives to sacrohysteropexy

i. Non mesh sacrospinous fixation

ii. Hysterectomy – only for a woman who has finished her family

iii. Colpocleisis – only for a woman who does not plan to be sexually active in the future

iv. Manchester repair -also known as the "Fothergill operation" -only for a woman who has finished her family

3. Alternatives to ventral mesh rectopexy for rectal prolapse/bowel disorders

Note: For a patient suffering from an external rectal prolapse, some form of surgery is usually needed. However, surgery is not necessarily needed for internal rectal prolapse (rectal intussusception) which may be a common finding in in healthy people. Surgery for internal rectal prolapse is normally done with the intent to improve symptoms of obstructive defecation/constipation or faecal leakage. But there is no way to differentiate causation and outcome with bowel symptoms and intussusception in terms of which causes which. Symptoms alone cannot distinguish the pathologic cause of functional constipation; non-pelvic floor problems, such as slow bowel transit or limited large bowel peristalsis, for instance, may underlie the symptoms of constipation and obstructive defecation.

https://gut.bmj.com/content/gutjnl/30/12/1737.full.pdf, https://www.wjgnet.com/1948-5190/abstract/v7/i12/1045.htm.

A. Conservative treatments for internal prolapse and obstructive defecation/constipation

i. Biofeedback

ii Pelvic floor retraining

iii Dietary modification

iv Trans-anal irrigation

v Osmostic, bulking laxatives

vi Stimulant laxatives

vii Prescription medications such as linaclotide or prucalopride

viii Sacral nerve stimulation

B. Conservative treatments for internal prolapse and faecal incontinence

i Biofeedback

ii Pelvic floor retraining

iii Dietary modification

iv Trans-anal irrigation

v Anti-diarrhoeal drugs

vi Sacral nerve stimulation

C. Non mesh surgery for rectal prolapse

I Delorme’s

ii Resection rectopexy

iii Suture rectopexy

MHRA Data from MHRA Adverse Event Report: Deaths recorded 2005-2015 related to mesh complications **Annex 13**

| **MHRA Adverse Event Report: Deaths recorded between 2005-2015 due to mesh complications** | | | | | | |
|---|---|---|---|---|---|---|
| **Device Description** | **Reported event type (detailed level)** | **Conclusion (broad)** | **Conclusion (detailed)** | **Outcome** | **Was the manufacturer contacted** | **Year Report Received** |
| Vaginal Mesh For Incontinence | Other Use error (Specify) | Use error | Other Use error (Specify) | Monitoring only,No further action required by MHRA or manufacturer | Yes | 2005 Q1 |
| SECTION TO ALLOCATE | Inadequate sealing,Other Use error (Specify) | No established device link,Patient's condition | Detached,Device performs as intended,Patient's Condition | No further action required by MHRA or manufacturer | Yes | 2005 Q2 |
| Vaginal Mesh For Incontinence | Cause not established | No established device link,No established use link,Patient's condition | Cause not established,Patient's Condition | Monitoring only,No further action required by MHRA or manufacturer | No | 2005 Q3 |
| RESORBABLE MESH | Patient's Condition | Patient's condition | Patient's Condition | Monitoring only,No further action required by MHRA or manufacturer | No | 2006 Q1 |

| | | | | | | |
|---|---|---|---|---|---|---|
| SILICONE MESH | Fracture of device,Weld/braze | Device design ,Mechanical failure | Excess device trauma ,Inadequate instructions | Design modified: unrelated to report ,Device recall ,Labelling / instructions modified | No | 2006 Q1 |
| SILICONE MESH | Fracture of device,Weld/braze | Device design ,Mechanical failure | Excess device trauma ,Inadequate instructions | Design modified: following report ,Device recall ,Labelling / instructions modified | No | 2006 Q2 |
| Vaginal Mesh For Prolapse | Other Use error (Specify) | No established device link ,No established use link | Patient's Condition | Monitoring only | No | 2008 Q1 |
| SILICONE MESH | Blockage | Device discarded ,Output/Function ,Patient's condition | Cause not established ,Difficult to remove | Monitoring only | No | 2009 Q3 |
| COLLAGEN MESH | Not to specification,Other Use error (Specify) | No established device link ,Patient's condition | Device performs as intended ,IFU not followed | Monitoring only | No | 2010 Q2 |
| POLYPROPYLENE MESH | [1703] Patient-Device Incompatibility | Compatibility ,Device discarded ,No established device link | Cause not established ,Migration | No action required by manufacturer | No | 2011 Q2 |
| POLYPROPYLENE MESH | [1703] Patient-Device Incompatibility | See main file | See main file | See main file | No | 2011 Q2 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Vaginal Mesh For Incontinence | [1703] Patient-Device Incompatibility | [26800] No medical device problem or failure detected | [26802] No medical device failure detected | No action required by manufacturer | No | 2013 Q4 |
| Vaginal Mesh For Incontinence | [1703] Patient-Device Incompatibility | Use error | Other Use error (Specify) | Monitoring only,No further action required by MHRA or manufacturer | No | 2015 Q4 |

Note: The above MHRA data on number deaths is in excess of previously reported deaths by MHRA in the same period. In the MHRA report, 2014: 'A summary of the evidence on the benefits and risks of vaginal mesh implants' MHRA reports that between 2005-2013 three deaths were recorded after mesh surgery to treat SUI and one death after mesh surgery to treat POP.

Annex 14

# MESH AND SURGICAL REMOVAL

**Sohier Elneil**

## INTRODUCTION

Continence and vaginal mesh implants were developed as simple flexible polypropylene plastic acting as a scaffold to treat urinary stress incontinence and pelvic organ prolapse respectively. It was deemed easy to insert, but no credence was given as to how it could be removed should it cause complications, or should it not be effective. It took less than an hour to implant and allowed women to leave hospital quickly and get on with their lives. Thus, rather than women undergo complex surgery, women were offered permanent mesh implants which became standard treatment for women with these conditions.

For many, mesh was initially seen not just as an effective treatment but as a permanent one. Complications were thought not be a significant issue and the figure of 1-3% was often quoted. However, we now know the complication rate was closer to 10% [1] and in many it was life-limiting. They included chronic pain, chronic infections, erosion into the surrounding organs including the vagina, urethra and bladder, as well as nerve and musculo-skeletal damage affecting mobility [2-5]. All have a significant impact on their quality of life.

It is as a result of severely debilitating complications following mesh implantation [2], that the field of mesh removal medicine and surgery emerged.

Early recognition of possible mesh complications is very important. It is normal to wake up in some degree of discomfort after any pelvic or continence surgery. However, if the pain after the operation is very severe and much more than expected after this type of surgery, it can be a sign that there was added trauma to nerves and blood vessels during the procedure. Most pain will be

managed with painkillers, but in some cases, women might not fully respond to the medication. If the pain is difficult to treat and does not improve over a few days, it might be necessary to remove the mesh. Leaving a painful mesh in the pelvis, can lead to chronic pelvic pain.

Removing an existing mesh is a complex procedure [6]. Each patient is approached on an individual basis depending on the type of mesh and extent of complications. This operation is done from the inside of the vagina. The surgeon makes a Y-shaped cut on the inside of the vaginal wall at the level of the bladder neck, and gently separates the two structures. The tube connecting the bladder to the outside of the body (the urethra) is lightly lifted off the vaginal wall and moved to the side, allowing the surgeon to tease the mesh off the walls of the urethra, vagina and bladder. Often there is also dense scar tissue in other areas of the pelvis such as the obturator fossa, pelvic side bones and vaginal skin that need to be removed. Once free of all the attachments the mesh can be cut and removed.

Removal of the mesh off the vaginal wall can make it thin, and often a surgical reconstruction of the urethra and bladder is required [7]. The operation takes 1-3 hours to perform. The deeper the mesh penetrates the urethral wall the longer you need to leave a urinary catheter in situ to allow optimal healing. Possible complications include:

- Bleeding
- Infection
- Damage to surrounding organs (bladder, urethra, nerves, blood vessels)
- Needing long-term urinary catheter 14 days to several months.
  In some cases, patients will need to learn CISC.
- Difficulty passing urine
- Blood clots (deep vein thrombosis)
- Fistula formation (an abnormal communication between bladder and vagina or uterus)
- Chronic pain
- Bladder problems such as recurrence of urinary incontinence, urgency, frequency
- New or worsening pelvic organ prolapse

Removal of mesh, whilst complex, does have beneficial outcomes generally. However, the long-term consequences after the mesh is removed can include chronic persistent pain, autoimmune

responses and complex neuropathies affecting the pelvis and the lower limbs [8]. Some of these can be treated effectively using a multi-disciplinary pain medicine approach. In other cases, the residual symptoms may require the input of an immunologist, rheumatologist or other symptom-defined specialist.

The alternative to mesh surgery for urinary stress incontinence includes physiotherapy or traditional surgical techniques. Studies have shown that over 70% who committed to physiotherapy for stress urinary incontinence often did not need any further intervention [9]. So, many clinicians are reverting to conservative measures first, before re-considering surgery. Clinicians are also now retraining in the traditional surgical techniques, which existed in the pre-mesh era, such as the Burch colposuspension and autologous sling.

**References**


1. Keltie, K., et al., *Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of 92,246 women.* Sci Rep, 2017. **7**(1): p. 12015.
2. Wang, C., A.L. Christie, and P.E. Zimmern, *Synthetic mid-urethral sling complications: Evolution of presenting symptoms over time.* Neurourol Urodyn, 2018.
3. Ubertazzi, E.P., et al., *Long-term outcomes of transvaginal mesh (TVM) In patients with pelvic organ prolapse: A 5-year follow-up.* Eur J Obstet Gynecol Reprod Biol, 2018. **225**: p. 90-94.
4. Mateu Arrom, L., et al., *Pelvic Organ Prolapse Repair with Mesh: Mid-Term Efficacy and Complications.* Urol Int, 2018: p. 1-5.
5. Cho, M.K., J.H. Moon, and C.H. Kim, *Non-absorbable and partially-absorbable mesh during pelvic organ prolapse repair: A comparison of clinical outcomes.* Int J Surg, 2018. **55**: p. 5-8.
6. Duckett, J., et al., *Mesh removal after vaginal surgery: what happens in the UK?* Int Urogynecol J, 2017. **28**(7): p. 989-992.
7. Shah, K., et al., *Surgical management of lower urinary mesh perforation after mid-urethral polypropylene mesh sling: mesh excision, urinary tract reconstruction and concomitant pubovaginal sling with autologous rectus fascia.* Int Urogynecol J, 2013. **24**(12): p. 2111-7.
8. Hansen, B.L., et al., *Long-term follow-up of treatment for synthetic mesh complications.* Female Pelvic Med Reconstr Surg, 2014. **20**(3): p. 126-30.
9. Ferreira, M. and P. Santos, *[Pelvic floor muscle training programmes: a systematic review].* Acta Med Port, 2011. **24**(2): p. 309-18.

Annex 15

# September 2018 Surveys of STM Facebook UK members

## Overview

A survey was carried out by Sling The Mesh in September 2018 of over 500 women who had mesh surgery in the United Kingdom.

One of the most striking observations is that almost a third (31.6%, figure 4) of the women surveyed noticed mesh related problems immediately after surgery. This contrasts with those who were diagnosed or acknowledged by a medical professional to be experiencing surgical mesh related symptoms. Only 6.2% of patients were recognised by a medical professional as having a surgical mesh problem within the first 3 months after surgery and only a further 3.6% patients were recognised by a medical professional within 3-6 months after surgery (Figure 5)

Overall 53.9% (figure 4) of patients had identified themselves as having mesh related complications immediately post surgery to 6 months after surgery, while only 9.8% had been recognised by a medical professional as having mesh related complications during that time (figure 5). We do not know how many of those patients who experienced mesh complications actually sought medical advice or diagnosis as data was not gathered but it is likely that those with early complications or symptoms would have mentioned their concerns to a medical professional, especially those (31.6%) who were aware of immediate problems while still in hospital.

Examination of the remaining data creates a clear picture of a mis-match between patient recognition of problems versus medical recognition of symptoms. Patients seem to be significantly “under-diagnosed” despite the clear narrative of hundreds of women who participated in the survey experiencing mesh-related problems. The data presented here represent only an initial analysis. What seems very clear however, is the contrast between patient reported problems versus medical recognition of problems and this pattern continues across the spectrum up to 22 years post-surgery.

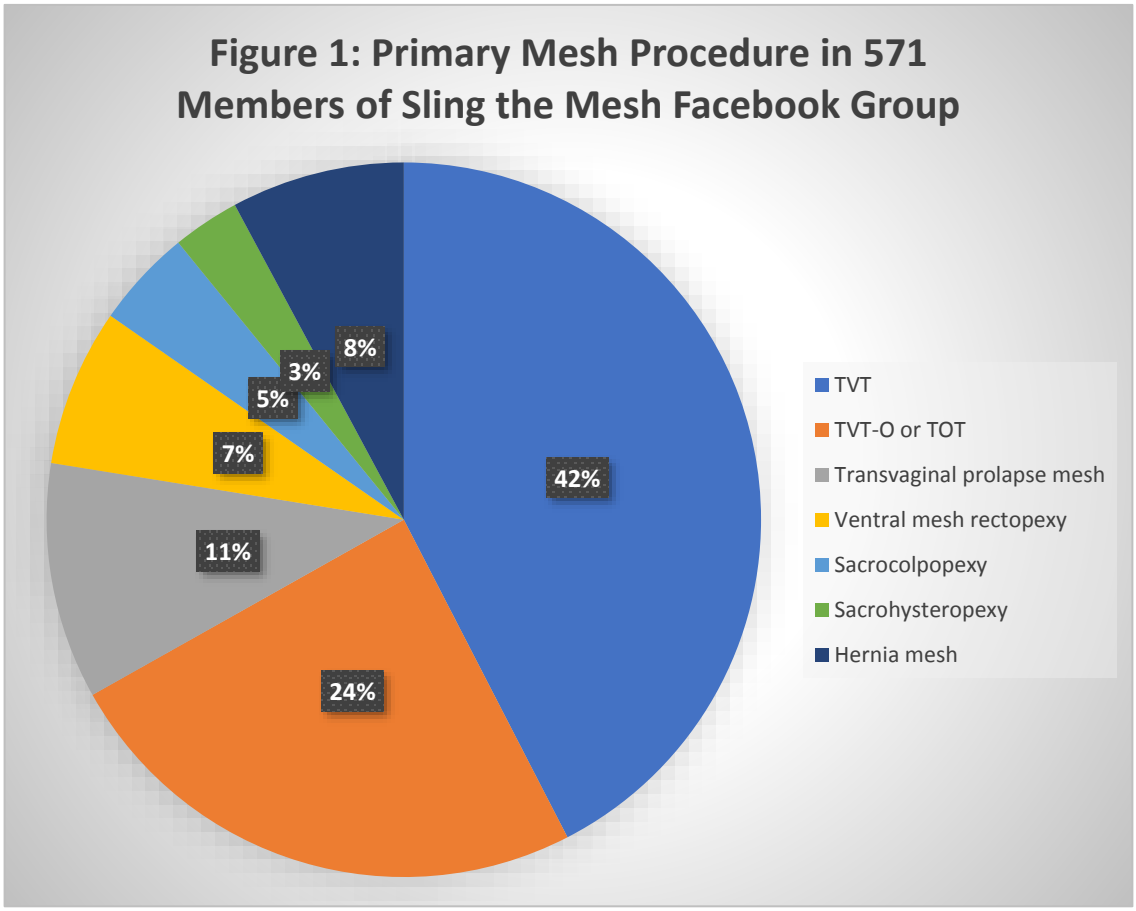



**Figure 1:** Frequency of primary mesh procedure from September 2018 Survey detailing 571 UK Sling the Mesh members' first mesh surgery by percentage. Survey conducted via SurveyLegend. Mesh types with a response rate of under 1% do not appear on chart.

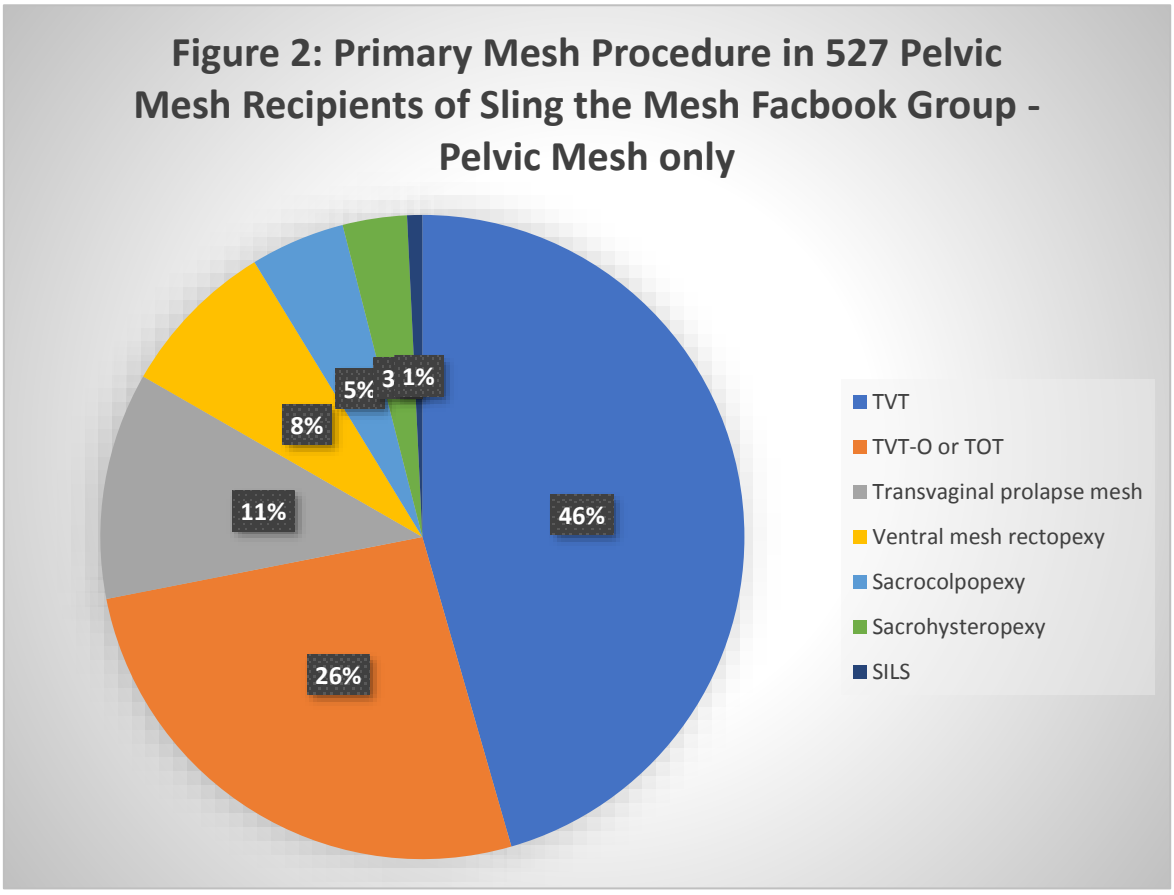



**Figure 2:** Frequency of primary mesh procedure type from 2018 Survey of 527 UK Sling the Mesh members with pelvic mesh placement. The 44 inguinal/abdominal hernia mesh respondents were excluded from this analysis.

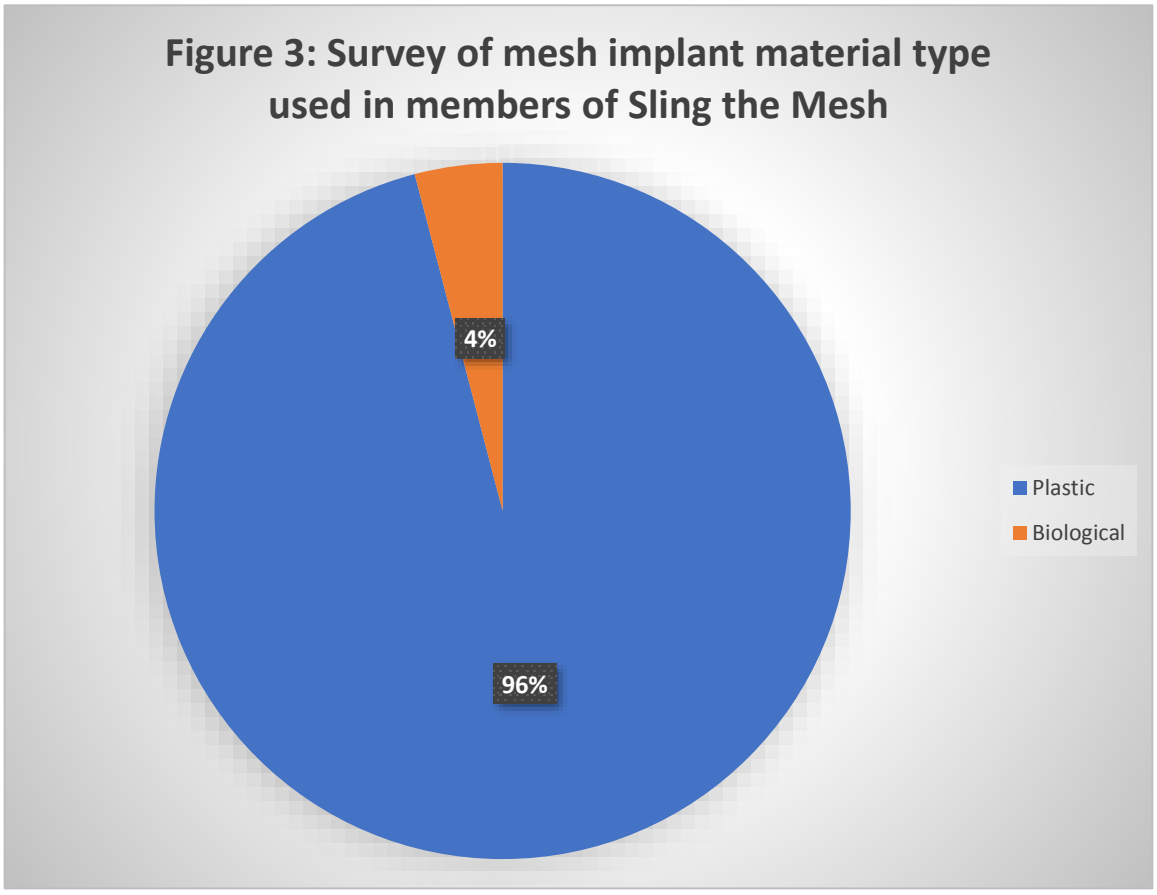



**Figure 3:** Mesh implant material reported by 541 UK members of Sling the Mesh in September 2018 survey. Respondents were asked the following question via SurveyLegend: "What type of mesh did you have: 1) Plastic (polypropylene) or 2) Biological (surgisis, permacol, xenograft, pigskin?."

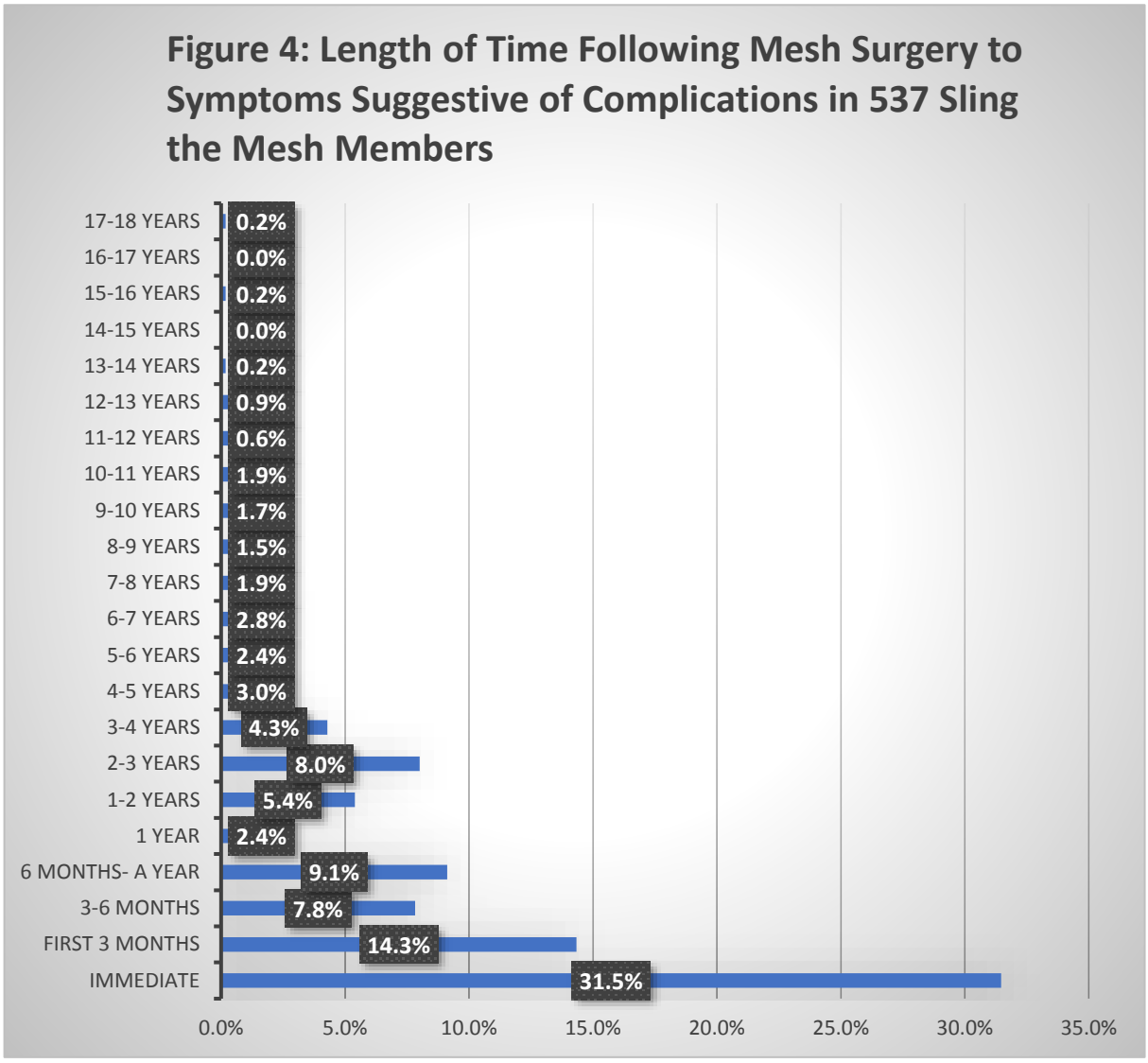



**Figure 4:** Length of Time Following Mesh Surgery to Symptoms Suggestive of Complications in 535 Sling the Mesh Members Respondents were asked the following question via SurveyLegend. “How long after mesh surgery did you begin to suffer from any complications/adverse events which YOU believed were as a result of the mesh surgery?”.

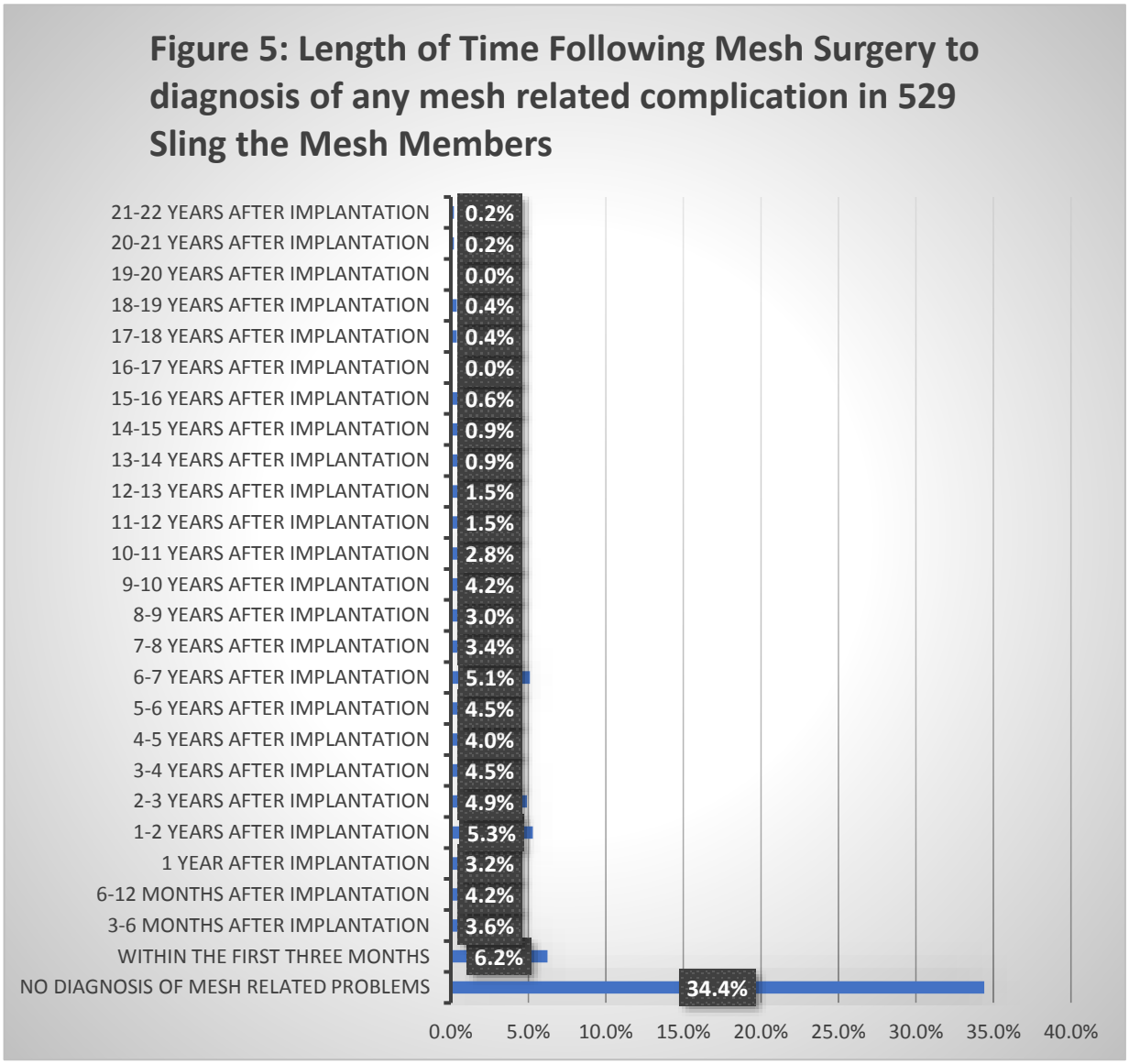



**Figure 5:** Length of Time Following Mesh Surgery to diagnosis of complications in 535 Sling the Mesh Members. Respondents were asked the following question via SurveyLegend. “How long after mesh surgery was it before any medical professional stated or acknowledged your mesh implant was causing you any complications/adverse effects?”

Welsh Mesh Survivors

# 1. Statement

WELSH MESH SURVIVORS

EVERY SINGLE ONE OF US SITTING IN THIS ROOM HAS BEEN DEVASTATINGLY HARMED BY A SURGICAL MESH IMPLANT ....

IMAGINE, IF YOU WILL, THE PAIN .....
LOOK AT THESE PICTURES - MANY OF THESE ARE OUR OWN PICTURES AND SOME HAVE BEEN SENT BY DIONYSUS VERONIKIS AN AMERICAN PELVIC MESH REMOVAL SURGEON.

WE HAVE ALL BEEN THROUGH THIS .... CAN YOU TELL WHICH WOMAN HAS BEEN HARMED BY HERNIA MESH? - PORCINE MESH? MESH USED FOR POP, SUI? YES, THERE ARE MEN SITTING HERE THAT HAVE BEEN HARMED BY MESH, TOO. WHICH ONES? CAN YOU TELL? ....

NO, OF COURSE YOU CAN'T TELL ...
BUT OUR PARTNERS, OUR FAMILIES, THEY CAN TELL YOU! THEY CAN TELL YOU BECAUSE THEY HAVE ALSO SUFFERED THE DEVASTATING CONSEQUENCES OF SURGICAL MESH IMPLANTS.

FOR EVERY PERSON THAT YOU SEE HERE, A WHOLE CLAN, PARTNERS, CHILDREN, THEIR MOTHERS FATHERS SISTERS BROTHERS BUT MOST IMPORTANTLY THEIR CHILDREN, HAVE ALSO BEEN HARMED.

SOME OF US ARE STILL GOING THROUGH HELL AFTER MANY YEARS BECAUSE THE SURGEONS COULD NOT REMOVE ALL OF THE MESH, STAPLES, POSTS AND SCREWS .....

PLEASE LOOK AT THE PICTURES AND IMAGINE SITTING, WALKING, STANDING - TRYING TO FIND A COMFORTABLE POSITION AT NIGHT. SLEEP ONLY COMES TO THE EXHAUSTED. SOMETIMES NOT EVEN THEN.

IF YOU HAVE EVER WALKED ON A SPLINTER OF GLASS, OR HAD TO WEAR ILL-FITTING SHOES FOR A FEW HOURS YOU STILL COULD NOT IMAGINE THE INTENSE PAIN THAT WE GO THROUGH EACH DAY.

THERE IS NO GOOD MESH.

[Items redacted]

Photographs of affected individuals, friends and family

Poster of affected individuals

Medical photographs (copyright)


## 2. Articles shared

BBC News. 6 September 2018. Inquiry call after mesh implant 'linked to woman's death'

https://www.bbc.co.uk/news/uk-scotland-edinburgh-east-fife-45430625

Sunday Post. 07 May 2018. Author: Marion Scott. Brave mum dying from cancer speaks out after controversial mesh treatment left her too weak for chemo

https://www.sundaypost.com/fp/brave-mum-dying-from-cancer-speaks-out-after-controversial-mesh-treatment-left-her-too-weak-for-chemo/

Sunday Post. 09 September 2018. Author: Marion Scott. 'There is a horrible pattern of women not being listened to': Mhairi Black backs dying gran's fight for victims of mesh

https://www.sundaypost.com/fp/there-is-a-horrible-pattern-of-women-not-being-listened-to/

# 3. FDA Reports of Adverse Events

I have enclosed some random reports from the FDA MAUDE public access site.

Also some research papers

https://www.ncbi.nlm.nih.gov/m/pubmed/22578730/?fbclid=IwAR1_PQ3ii7a0QYOPTGaGXVLp7K5RJqNSVzAz2JiYNrbkvlzCV9tHCaZJshc

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2749389/

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2999770/

Above: Repair of hernia Lichtenstein method and the Shouldice method

- no mesh.

These are named units in England agreeing to see women with prolapse after Mesh complications and also women with Mesh Complications. At least three of those Consultants are held in abhorrence by Mesh Survivors, due to the fact that they feel those people ruined their lives by implanting Mesh. There will of course be huge trust issues.

https://bsug.org.uk/budcms/includes/kcfinder/upload/files/Units%20with%20completed%20returns%20MASTER%20September%202018%20v3.pdf

And then there are concerns over titanium implants.

Many Meshes are, as we've said in other evidence, implanted using titanium screws and staples.

https://www.sciencedaily.com/releases/2011/07/110725101257.htm

FDA Adverse Events:-

Please take note of the dates of implantation and the reporting of these these Adverse Events.

Also note that in one Adverse Event the Mesh sis not even make it into the Patients body before it tore!

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/textResults.cfm?dls=81&q=SGVybmlhIE1lc2g=&pf=2018&pn=10&sc=

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7574598&pc=FTL

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7292447&pc=OTN

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7292800&pc=OTN

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7338204&pc=FTL

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7337506&pc=FTM

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7343366&pc=FTL

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7342827&pc=FTL

# Welsh Mesh Survivors

Welsh Mesh Survivors would like you to add the above reports and research to these letters below, outlining our work with the Welsh Government.

I hope that you can make sense of all of this work below, and that it demonstrates that EVERY UK Mesh Survivor is singing from the same page. We may not all work co-hesively, but at the end of the day we do all want the same thing.

WELSH MESH SURVIVORS ARE CALLING FOR A COMPLETE BAN ON THE USE OF ALL SURGICAL MESH DEVICES. WE WANT TO SEE A FULL UK INVESTIGATION AND PUBLIC INQUIRY INTO THIS GLOBAL MEDICAL HEALTH DISASTER.

WE WANT TO MAKE IT CLEAR THAT MEN AND WOMEN MESH SURVIVORS WILL NOT BE DIVIDED - WE HAVE ALL BEEN DEVASTATINGLY INJURED BY SURGICAL MESH IMPLANTS,

PELVIC MESH, HERNIA MESH, PORCINE MESH, RECTOPEXY MESH.

**********

Letter to CABINET HEALTH SECRETARY VAUGHAN GETHING

Monday 22nd January 2018

Meeting to discuss Complications of Surgical Mesh Devices

Welsh Cabinet Health Secretary for Health and Social Services

Vaughan Gething

Jane Hutt AM

Ty Hywel building

Pierhead Street,

Cardiff Bay

Thank you for agreeing to see the representatives of our Welsh Mesh Survivor Support Group to discuss Surgical Mesh Device Complications in an attempt to find a way forward to avoid other people suffering the injuries and pain that we go through on a daily basis.

After consultation with our group, there are many proposals that have been put forward for discussion, we have decided to outline issues we feel are the most important.

> Welsh Mesh Survivors urge Welsh Government most strongly to suspend the use of Mesh, in-line with Scotland, pending a full investigation into it's safety. We urge the Welsh Government to hear our voices, particularly as

> New Zealand has a blanket ban on ALL pelvic Mesh

> Australia has now banned many of its Surgical Mesh devices.

> The FDA in America has re-classified Surgical Mesh Devices to high-risk.

> The FDA has re-classified the surgical instruments which are used blindly to insert and attach the Mesh used in these procedures, e.g. the Trocars

>The EC has also re-classified the use of mesh to high-risk.

>NICE has now put forward evidence based recommendations that certain Mesh procedures should be discontinued because the risks and complication rate is too high.

Please, please heed all of these warnings from all over the world!

> The reporting of complications of Surgical Mesh Devices must be mandatory. Surgeons do not at present report or compile accurate figures of the complication rates. Therefore only the the NHS figures exist - 1 in 15 women having removal of their Mesh. An absolutely shocking disgrace, and this in no way deals with the private sector which also fails to log long-term complications or the repair of failed Mesh, such as trimming, or 'shoring up' of the Mesh with MORE Mesh = Hidden figures of complication rates.

THIS must be investigated.

> A register of Patients implanted with a surgical device must be implemented and should be logged in a UK database and tracked for as long as those Patients live.

Surgical Devices must be tracked in the same way as aircraft and vehicle manufacture.ALL Surgical Mesh Implants, whether they may be used to repair Hernia, POP or SUI should all be regulated in this way.

> Follow-up should be long-term, and every adverse incident logged, including suicide People have come forward to the Support Groups as many as 18 years after implantation, with horrific complications.

A register of Mesh injured people should be compiled and all further complications and deaths noted, even if they seem unrelated including suicide

Many have developed auto-immune disease brought on by the serious complications of a failed Mesh implant. Many, many 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

Patient SAFETY should always come first and foremost. This alone should be the main focal point at issue - NOT Patient Consent.

EVERY Patient/Consultant discussion should hold the words 'Surgical Mesh' 'Surgical Mesh Ribbon' or 'Surgical Mesh-Tape'

We are finding that Surgeons are hiding or disguising the word MESH and even telling Patients that they will be using a 'ribbon' or 'tape' or SAFE Mesh.

There IS no safe Mesh.

> The treatment of Patients already injured by Mesh is, in our experience, woeful.

There are no true statistics of adverse events or complication rates because incidents are seriously under-reported by Consultants and there is no guidance to Patients to report using the Yellow Card Scheme.

This must all be addressed as a matter of urgency.

Within the documents that we have enclosed is a map of UK places of 'Specialist Treatment Centres' for Mesh injured patients. You will see that there are NONE marked in Wales - We do NOT have a specific 'Specialist Mesh Complications Clinic' set up in Wales.

We urgently need one!

More and more Welsh people are approaching the Support Groups seeking help and information every day.

There is a great need for sympathetic Consultants with a good experience of Mesh Complications, and expertise in Mesh Removal. Sympathetic Medical Staff who will be used to dealing with patients suffering from chronic pain and infection.

Welsh Government must implement improved training for GPs and Consultants to recognise and understand the symptoms of a failed Surgical Mesh Implant.

There is an urgent need for specialist treatment, and scanning equipment to be made available in order to view the Mesh implants. Trans-labial Scans are so important to visualise the Mesh. It seems that MRI CT and Trans-vaginal scans are completely inefficient.

Trans-labial scans must be made available in Wales.

Mesh Survivors are continually fobbed off or made to feel humiliated, particularly by their Mesh Surgery Consultants. Often they are referred back to the implanting Consultant for Mesh repair or Mesh Removal Surgery of the failed implant.

This is not acceptable.

If the funding is not available for Welsh Government to supply Survivors with a Specialist Mesh Complication Clinic, then Mesh Survivors should at LEAST have

> cross-border funding made available to visit a Consultant that we feel we may trust.

Far too many of our Group Members are either being told by GPs that the funding will not be available for cross-border treatment and those who take their application for funding to their LHB are being turned down. The Mesh injured patient is often referred for a second opinion to Consultants we feel are affiliated in some way to our implanting Surgeon or to someone we may feel is going to be biased towards the continual use of Surgical Mesh.

> We need access to a Mesh Complications Help-line, such as the one set up in Scotland and also we are told that there are plans to introduce one in England.

If there are not sufficient funds to set one up in Wales, perhaps we could eventually access the planned English Mesh Complications Helpline.

> PIP and Disability Assessors must be fully informed about Mesh Complications and injuries, such as organ and nerve damage, bowel and bladder injuries and highly embarrassing personal problems such as stress urinary incontinence or dual incontinence. Assessors must be fully informed and have a better understanding of the fact that Mesh injuries are invisible and cannot always be demonstrated. We are often discriminated against in many ways due to misguided benefits personnel

> This also applies to the application for Blue Badge disabled parking.

> In the future, we would hope that increased funding will be made available for the training of Doctors and Surgeons in improved surgical techniques using native tissue to repair POP, SUI and Hernias.

> On Tuesday February 6th 2018 'Sling the Mesh' Campaigners will be at The House of Lords where Lord Phillip Hunt will ask

“Why aren’t Ministers following New Zealand in banning the use of Mesh in Pelvic Operations? …. ”

Welsh Mesh Survivors today ask this same question of the Welsh Government

Yours Sincerely

The Welsh Mesh Survivor Group Representatives:-

Nicola Hobbs

xxxxxxxxxxxxx

Jemima Williams

**********

Letter to WELSH CABINET SECRETARY FOR HEALTH VAUGHAN GETHING

Welsh Mesh Survivors would like to thank Vaughan Gething and his Task and Finish Group for carrying out this report. However we do feel great concern that what is proving to be a serious global health disaster could have been dealt with in such a short time as four months and we feel that the recommendations don't go far enough.

We are happy to see the work that was submitted by Global Mesh Survivors was added to the report and also that the Patient Experiences were added.

There are many positive aspects to this report if the funding can be made available, but there are also many disappointing negatives and in truth in the short amount of time we were given to look over this report it will be impossible to address all.

Here are a few - minus statistics at this time of the early hours.

> The recommendations we made for a better health-care pathway for the Mesh injured seem to have been listened to, but we feel that the plans put in place for our care will not be enough:-

> Just TWO Uro-gynaecological Mesh Removal Experts to cover the whole of Wales is a horrifying thought and we have no confidence in the idea that they may also be implanting Mesh - We seem no further forward at all and envisage major trust issues with Consultants that some of us may feel have already caused us distress or harm.

> And though the report says that all Health- Care professionals must understand Mesh issues how do they propose to instil this understanding? no protect further patients from harm.

We are happy that our added suggestions for physiotherapy as prevention of SUI and POP are being implemented.

> It is glaringly obvious from this report which took just a few months to prepare that we need a Welsh Audit within the NHS AND the Private Health Sector, looking into the use of Mesh and its complications - particularly as the English Audit showed Mesh complications to be, alarmingly, much higher than UK Government first thought.

Therefore, Welsh Mesh Survivors are once again urging our Government to call for a suspension on the use of Surgical Mesh implants pending a full independent public inquiry, this should be implemented immediately. Not one more person should be harmed. ***

There are many positive aspects to this report, but also there are some disappointing negatives.

> There seems to be disbelief within the Task and Finish Group at the amount of women suffering with Mesh complications in Wales. The reference to this 'small number of women' that contacted Government via email, we thought was appalling and patronising, especially since the Membership figures of UK Mesh Survivor Support Groups are now reaching upward of 10,000 people across the UK, and many of them are Welsh.

It is good to note that the use of surgical mesh has gone down in previous years, but Mesh survivors fear that the more robust consent and information packages, will send mesh use soaring once again. We do not believe that information leaflets alone will address warnings of the severity of complications and the thought that there are only TWO Consultants considered to be expert in Mesh Removal covering the whole of Wales is horrifying! And if they are also implanting Mesh?- Where does that leave patients suffering complications? We are still in a Catch 22 situation. That hasn't changed.

There is so much more to add to this !!!!!!!!!!

The use of Rectopexy Mesh needs to be addressed urgently, particularly as Emma Hardy MP in a recent Westminster debate trounced the Pelvic Floor Society that recommends this as 'safe' in view of its conflict of interest - it's links to industry and funding by mesh manufacturers. In Mesh Survivors experience this is one of the worst Mesh Devices to have ever come on to the market. The complications from Rectopexy Mesh is absolutely horrendous.

> An encouraging positive made reference to in this report, and we hold Vaughan Gething to it, is his personal assurance that he will also look seperately into Hernia Mesh.

There also needs to be an Audit into Hernia Mesh.

> Another of the main positives is that there will be a complete emphasis on referral to Physiotherapy as soon as women present with a problem. Studies in Cardiff have proved that with support and encouragement this works effectively.

However, the report goes on to say that there are at present only 17 Physiotherapists covering the whole of Wales and says this will be addressed.

**********

WELSH MESH SURVIVORS STATEMENT:

VIEWS ON THE TASK AND FINISH GROUP REPORT.

LET US BEGIN BY THANKING WELSH CABINET HEALTH SECRETARY VAUGHAN GETHING AND HIS TEAM FOR ALL OF THEIR EFFORTS.

MY OWN PERSONAL THANKS GO TO JANE HUTT AM AND INDEED ALL GOVERNMENT REPRESENTATIVES SUPPORTING THE SURVIVORS.

> THERE ARE MANY POSITIVE ASPECTS TO THIS REPORT AND THERE ARE ALSO MANY NEGATIVE ASPECTS AND UNANSWERED QUESTIONS, BUT PERHAPS THIS POINTS TO THE FACT THAT THIS REPORT, LOOKING INTO A VERY SERIOUS HEALTHCARE DISASTER WAS RUSHED, OVER A VERY SHORT PERIOD OF THREE OR FOUR MONTHS.

WE FEEL THAT WE NEED TO ADDRESS ALL ISSUES OF THIS REPORT VERY CAREFULLY, BUT WE WERE GIVEN THIS 83 PAGE REPORT JUST A FEW DAYS AGO. NO TIME AT ALL.

> OUR GOVERNMENT ARE TELLING US THAT THE MHRA ARE ULTIMATELY RESPONSIBLE FOR THE USE OF SURGICAL MESH DEVICES IN OUR HEALTHCARE SYSTEM AND THAT ONLY THEY, THE MHRA, HAVE THE POWER TO SUSPEND ITS USE .

***WELSH MESH SURVIVORS BELIEVE THAT OUR GOVERNMENT SHOULD, IN LIGHT OF THE ENGLISH AUDIT, BRING POWER TO BEAR ON THIS GOVERNMENT ADVISORY BOARD AND INSIST THAT THEY SUSPEND ITS USE, PENDING A FULL INVESTIGATION AND PUBLIC INQUIRY INTO THE USE OF MESH AND IT'S COMPLICATIONS .

WE FEEL It is glaringly obvious BY READING THE TASK AND FINISH REPORT that we need a Welsh Audit within the NHS AND the Private Health Sector, particularly as the English Audit showed complications to be, alarmingly, much higher than UK Government first thought.

> The NHS own figures of 1 of 1 in 15 women undergoing surgery to remove a failed Surgical Mesh device tells it's own story and the same figures apply here in Wales.

**** The report is headed by a quote by Dr Martin Luther King jnr

which WELSH Mesh Survivors put inside the boxes of evidence that we provided for Vaughan Gething -

***OUR LIVES begin to end the day we become silent about things that matter*****

***Let us not forget that Dr Martin Luther King jr stood alone and was the mouthpiece for millions.

**** > Welsh Mesh Survivors declined to join the Task and Finish Group detailing the reasons why in an email that we sent to Group Members, the key features of that email was that we were given only four days to prepare for the first meeting and also there was an an issue with the fact the Chair was a Uro-gynaecologist whom at least eight of our Welsh members felt that they had issues of trust.

>The report's numbers detailing how many women were writing to Government and the contact emails from Mesh Survivors we feel is wrong and their implications of this are both appalling and patronising.

> Mesh Survivors are telling YOU that in the UK alone we know there are over 10,000 Mesh Survivors belonging to the main UK Support Groups and that is not including the smaller splinter Groups around the UK, or our e-mail contacts.

Over 10,000 devastated families…

And these are just the people that actually realise and know that they have complications. There are a lot more people out there still being told that they are 'unique' by doctors and healthcare professionals that either don't have a clue about Mesh Complications or are in fact denying that there is a problem.

There are many positive aspects to this report providing the funding can be made available, but there are also many disappointing negatives and in truth in the short amount of time we were given to look over this report it would be impossible to address all of the contents at this time.

> The fact that Intense Physiotherapy is going to be made available right across Wales, is massive and of great emphasis during this report, but the fact that there are only 17 Physiotherapists to cover the whole of Wales is shocking, the report says that this is being addressed.

> Better facilities for Mesh injured Women are being set up in Wales, but only TWO Uro-Gynaecological consultants expert in Mesh Removal to cover the whole of Wales, - THAT is horrifying! - TWO, - both of whom have more than likely implanted Surgical Mesh into us, ruining our lives and with whom we may now have trust issues. Also the better information for patients leading to more robust consent will still only be as good as the patients are led to believe and understand unless there is great counsel.

** There is no mention of cross-border funding for referral to Mesh Removal Experts trusted by the Mesh Survivors.

> We are very pleased to note that a promotion of better understanding of Mesh Complications by Health-care Professionals and by the DWP and Benefits Assessors will be implemented to help explain what has, up to now, been a hidden and an embarrassing taboo subject , one which heavily discriminates against Mesh Survivors both Men and Women.

**There is however, no mention as to how these measures will be implemented.

Therefore, Welsh Mesh Survivors are once again urging our Government to protect it's citizens and call upon the powers that be for a suspension on the use of Surgical Mesh implants pending a full independent public inquiry, this should be implemented immediately - Not one more person should be harmed.

The Welsh Government has NO idea of the true scale of statistics of this health disaster, Global Health disaster which medical experts like Prof Carl Heneghan Editor of the BMJ says is worse than Thalidomide. Carl Heneghan also said in

a recent address to UK Government's APPG looking into Mesh "Nobody ever died from peeing their pants, but Mesh complications can be fatal"

> THE 'TOOLS' USED AS GUIDES FOR THIS CARE-PLAN ARE FIRSTLY, THE

SCOTTISH REPORT WHICH WAS BRANDED A 'WHITEWASH' BY CAMPAIGNERS AND THEIR GOVERNMENT REPRESENTATIVES.

*** SCOTTISH MESH SURVIVORS WISH PEOPLE TO KNOW THAT THEY ARE NOW SUING THEIR GOVERNMENT FOR REFUSING TO WITHDRAW THEIR INPUT AND THEIR NAMES FROM THIS REPORT:-

THEY SAY

**"The Scottish Government Final Report was branded a whitewash. The review process is currently under review and until this investigation concludes and publishes, the Final Report is certainly not something the Welsh Govt should be aspiring to."**

**AND WE ARE NOT SURE WHETHER THE FRENCH MESH TRIAL REFERRED TO IN THE WELSH REPORT MAY HAVE BEEN THE ONE THAT WAS DAMNED BY AUSTRALIAN SURVIVORS AND THEIR LEGAL REPRESENTATIVES. - AS REPORTED IN THE GUARDIAN ON 10TH JULY 2017**

**THIS GLOBAL HEALTH DISASTER IS A SHOCKING DISGRACE ON OUR SOCIETY AND ON OUR HEALTHCARE SYSTEM**

> IN THE GUARDIAN THIS MORNING - Private hospitals were given two weeks by #JeremyHunt to investigate and implement changes after a report shows a third of private hospitals must improve while there are fears for safety at 41% of them. There's 206 private hospitals in England. That's a lot of failed patient safety.

The private sector has been v busy implanting mesh for the last 20 years with no audit whatsoever and no data on complications for the Government mesh audit.

Wake UP, Wales. Suspend the use of Mesh.. Audit the NHS and the Private Health Sector. Independently, and publicly investigate the use of Mesh and its complication rates. Protect future patients from harm.

JEMIMA WILLIAMS - ON BEHALF OF WELSH MESH SURVIVORS

**********

Jane Hutt AM addressing The Senedd:

Cabinet Secretary, are you aware of the research being undertaken at the University of Sheffield, published in the journal 'Neurourology and Urodynamics', which supports the use of a softer and more elastic material, better suited for use in the pelvic floor, and one that releases oestrogen into the surrounding pelvic tissue to form new blood vessels and ultimately speed up the healing process? They concluded that a different material, polyurethane, would be a much better material to use as a vaginal mesh due to its flexibility and its likeness to human tissue. The next step is clinical trials. Cabinet Secretary, can you ensure that Welsh patients have access to these trials?

Can I thank the Cabinet Secretary for your statement today and can I welcome the recognition, at long last, of the adverse impact of the use of synthetic tape and surgical vaginal mesh sheets for treating pelvic organ prolapse and stress urinary incontinence, leading to appalling, long-term and life-changing consequences for women's health? I welcome the recommendations in your report that relate to preventative measures and conservative management of these conditions and with surgery as a last resort. I welcome also, for example, the recommendation for a new pelvic health and well-being pathway. And can I thank the Cabinet Secretary for meeting with my constituents, Jemima Williams and Nicola Hobbs, whose lives have been so adversely affected by vaginal mesh implants? I'd like to praise them for their courage and their leadership in the Welsh Mesh Survivors group. But can I clarify, Cabinet Secretary, the position regarding my constituents, Jemima and Nicola, and the task and finish group? Because in your written statement you said that they chose not to take part in the group, but can I draw attention to the context of their decision not to take engage? They were deeply concerned about the membership of the group, the papers presented to the group and the lack of notice and draft terms of reference, because both also are suffering from constant pain and severe ill-health.231

But it was very helpful that you agreed to meet them, with me. Can you confirm that you took full account of their full and harrowing evidence at that meeting? They did provide an extensive folder of patient experience of adverse impact. And also, can you confirm and clarify, Cabinet Secretary, what cross-border engagement is taking place to share clinical expertise, evidence from patients, mesh sufferers and funding also that could be available for referral to mesh removal experts?232

Finally, as you are aware, the Welsh Mesh Survivors group are calling for mesh use to be suspended until a full audit has been carried out. And it's hard to believe that the procedure can still take place in Wales, despite the point that you made today in your statement, that all reviews to date have shown how difficult it has been to have a reliable assessment of the scale of the problem that can be linked to the use of vaginal mesh. That is as we are today. So, Cabinet Secretary, will you consider holding a retrospective audit of the use of mesh in Wales and consider suspending the use of vaginal mesh until this takes place? Thank you.

**********

The First Meeting of WHIG: Women's Health Implementation Group, set up by Welsh Cabinet Secretary For Health  Vaughan Gething:

(DEAR TEAM; I apologise, this was supposed to have been the last in line of all of this work)

20th September 2018

First meeting WHIG Women's Health Implementation Group

Bore da pawb/Good Morning to all

xxxxxxxxxx - WE are all Welsh Mesh Survivors. We would like to thank you, the Chair of the Health Implementation Group, for facilitating this meeting and we hope that we can all amicably forge a pathway which will be beneficial to all

We would like you to realise that though this Implementation Group has been set up by Cabinet Health Secretary Vaughan Gething in order to help Women injured by Pelvic Mesh, there are many many women and MEN whom have also been devastatingly injured by Surgical Mesh implants for hernia repair, and we, as Survivors of this global health disaster, have made a vow to support each other through thick and thin.

We understand that in order to help us, Welsh Government feel that they must separate us into groups, but many of us feel angry at this and we feel that this division is discriminatory. Vaughan Gething, in his statement to the Senedd on May 8th of this year, almost five months ago, promised Welsh Mesh Survivors and our Government Representatives that he would "look into Hernia Mesh" We have not been made aware that he has done so, as yet, and we would like his assurances that he WILL do so.
**We feel that ALL cases of failed mesh surgery must be "looked into" meaningfully AND WITHOUT DELAY
** Really, it goes without saying that EVERY Mesh injured patient should be treated with the greatest of compassion and expert medical care.

It has been reported to us, by Health Professionals working in certain hospitals that even during this restriction/halt/pause on the use of Surgical Mesh in Wales, that this operation is still going on, this is NOT acceptable.

In order to make a start on this journey together, Welsh Mesh Survivors have agreed to come here today, to discuss a way forward through this Mesh Hell and also discuss the need for specialist care and equipment in places of expertise for ALL of the Welsh people injured by Surgical Mesh Devices.

We feel that £1,000,000 is not going to stretch very far, but it is a start…

We understand that the implementation group has to explore how to divide this sum of money, between what we feel are approximately four categories.

Welsh Mesh Survivors feel that Patients already injured by Surgical Mesh Devices should URGENTLY be given first priority WITHOUT ANY MORE DELAY :

>> Category A) Treatment of Patients already harmed by Surgical Mesh implants:

(i)Training of specialist Surgeons - Uro-Gynaecologists and Colo-Rectal Surgeons to repair SUI/POP/Hernia without using Surgical Mesh implants, but instead using native tissue, and even more importantly they must be expert in removal of ALL of the mesh and anchors/staples, safely and successfully.
(ii) After removal how to treat and manage mesh injured patients with chronic pain and complications such as auto-immune disease.
(iii) The places of specialist expertise would need funding for specialist equipment and diagnostic tests - i.e. Translabial Scans made available for women presenting with Mesh complications, or equivalent MRI or CT scans for Patients suspected of suffering Mesh related adverse symptoms - many hospitals are already equipped with these scanners, but they need to be operated by specially trained staff. Funding must also be set aside for urodynamics and defecatory disorder diagnostics - ALL of which some patients have been denied due to lack of funding at their local hospital.
**We need to stress that in all cases speed must be paramount. Our lives, or what is left of them, are being destroyed. The longer we are left in our current situations, the more harm is being done (and in most cases the more it will then cost them to put matters right). Gaps of 14 months between consultant appointments (many have experienced long

delays between appointments!) are simply not acceptable and patients with post-mesh complications need to be automatically upgraded to URGENT status. Similarly, sending sufferers back to the surgeon who originally caused the problem must stop now. We already know those surgeons will be less than sympathetic - particularly in cases where there was no meaningful consent, as those surgeons know that they are already in jeopardy of civil litigation.
** Taking the above points into account there needs to be an urgent change to the protocol on cross-border referrals. As most of the skills and resources to help put right the harm done by mesh implants exist outside of Wales, a cross-border referral for a mesh-injured patient should no longer to subject to local vetting and until Vaughan Getting's places of expertise have been put in place many of us need URGENT cross-border funding.

(iiii) There must be also be urgent direction to the DWP and Benefits Assessors regarding Mesh Complications, too many of us are discriminated against due to the private and highly taboo nature of our injuries. Assessors need to be much more sympathetic to Mesh injured patients specific problems.

Ideally there should be at least three of these specialist clinics in Wales, preferably manned by experts with an 'Anti-Mesh' philosophy.

>> Category B) GP and Consultant Awareness:

There must be urgent training of GP s, Consultants and their Teams to be made aware of complications of Mesh implants and to learn of the symptoms of adverse effects of Surgical Mesh, to ensure
(i) Early diagnosis of surgical mesh complications
(ii) How to actually refer to specialist places of expertise
(iii) After referral, how to manage ongoing complications/problems of their chronically ill mesh injured patients.
(iiii) Compensation/ Financial Support of Mesh Survivors and Sufferers must also be addressed. Many of us are now too ill to work to help support our families and may need specialist help and equipment placed in their homes to help with safety and mobility.
Please be aware that many of us have had to pay privately to have tests and scans and the financial outlay for this has reached massive proportions for some.

**Please also note here that there are men and women going through mesh complications whom are in absolute agony and so physiotherapy is NOT an acceptable treatment for them. Exercise whilst you have, what can only be described as a cheese grater in your groin or pelvic region, is not only extremely painful, but in our own experience can be very dangerous.

**It is fair to point out that there will inevitably be Legal Action taken against the Manufacturers and/or Surgeons in future - We feel that they should be held accountable and made to pay into this fund.

>> Category C) Patient's presenting with injuries/symptoms of POP/ SUI / Hernia

(i) There is an urgent need for Physiotherapists with expert knowledge in how best to treat and heal pelvic floor and hernia injuries.
(ii) Urodynamics testing is essential in detecting the extent of Pelvic floor injury. Funding must be made available for this.

Surgeons should be highly trained in native tissue repair. The patient should be fully informed of all options available. Only in EXTREME cases should Patients, for whom there is absolutely no other solution, be treated with a Surgical Mesh Implant, and then only AFTER being given all of the facts, full disclosure of the potential risks, complications and the complication rates. This education of the patient should be via information booklets sent to their home at least a month before the operation, so that the patient can then discuss all of these factors with their family before making a final and fully informed decision. Only then should a discussion between Consultant and Patient go ahead. The operation should not go ahead unless there is surety that the patient has full understanding of the potential hazards of this operation.

This operation should not go ahead until the the following procedures are put in place:-
(iii) Computer coding, documentation and registration of EVERY Surgical Mesh Implant - both nationally and patient home-held record of implant in case of future adverse events.

(iiii) Life-long follow-up of patients.
(iiiii) Mandatory reporting by Surgeons and GP s of Surgical Mesh Adverse events to MHRA and guidance to Patients to also report adverse events to MHRA.

There should also be assurances from Government that despite Patients having been fully informed and consenting to this operation, this will not lead to any future discrimination against them.

>> Category D) Prevention is better than cure:

Funding for the training of Specialist Physiotherapists to prevent POP and SUI in young women of child-bearing age and also advice on prevention of hernias, in both women and men, through physiotherapist-led lectures:-
(i) In School's Sex Education lectures for pupils age 15+
(ii) Contraceptive Clinic (what better time to focus young people's attention?) Specialist Nurse-led, or GP in-put with the help of explanatory leaflets.
(iii) Anti-natal and Post Natal clinics. Midwife and Physiotherapist- led lectures and pelvic floor exercise.

**********

Welsh Mesh Survivors have been writing and emailing Government since approximately 2011 to warn them of the rising numbers of Mesh injured people in Wales and indeed globally.

As a direct consequence of this pressure and also the sudden and intense media coverage, Cabinet Health Secretary of Health for Wales, Vaughan Gething decided to carry out an investigation.

Vaughan Gething set up The Task and Finish Working Group and representatives of our Support Group were also invited to attend the meetings.

We were soon to realise that Mesh Survivors were going to be marginalised - we were only given notice just four days before the first meeting was to go ahead. The Chair of this group was a Consultant that many felt had ruined their lives. Welsh Mesh Survivors felt that we had to decline the invitation.

We did, however, put together a lot of research and Welsh Mesh Survivor accounts and experiences of Mesh Complications. We requested a meeting with Vaughan Gething to point out the reasons that we felt that we could not accept the invitation to the Task and Finish Group.

*****This is a copy of the e-mail that Nicola Hobbs and I sent to as many members of the Task and Finish Working Group and also to the Welsh Cabinet Secretary of Health Vaughan Gething and his Officials.

It was with deep regret Welsh Mesh Survivors decided that we could not work with the Task and Finish Working Group.

10/17/17

** FAO of the Chair, Professor Simon Emery and All Group Members of the 'Task and Finish' Working Group.

It is with deep regret that my colleague Nicola Hobbs and myself will be unable to attend the first group meeting.

We both believed when we were first approached that this working group was going to be a major step forward in Wales, an investigation into the Safety of Surgical Mesh Implants, with Patient Safety being it's focal point. We hoped that this would lead to a call for the suspension of Surgical Mesh Implants.

We also believed that this would cover Hernia Mesh Implants along with Mesh used for POP and SUI. We have many men and women on our Mesh Support Sites who are dealing with complications due to Hernia Mesh. We feel it would be a dereliction of our duty of care towards those members to continue without their representation.

Nicola and I read the Agenda with deepening disappointment, noting that the attachments include both the English Review Report and the Scottish Review Report. These in the eyes of all Mesh Campaigners are completely flawed and have been called a 'Whitewash' by the Patient Representatives on those Groups and also their all-party supporting Government Ministers.

xxxxxxxxxxxx and xxxxxxxxxxxxxx resigned from the Scottish Working Group because despite all members agreeing to the interim report, the final report which was actually published earlier this year was found to be incomplete. Chapter 6 had been completely deleted from the report and certain words had been obliterated throughout, leaving the Patient Representatives feeling that the balance of the report had been completely changed and had become, in fact, biased towards the use of Surgical Mesh.

xxxxxxxxxxxxx words, spoken to an all-party Petitions Committee which I was invited to attend at Holyrood, were that both xxxxx and xxxxxx felt they had been "duped and marginalised" by the working group and that they had been used as "window dressing" for this flawed report. They asked that their work be withdrawn from that report, but it went ahead and was published without their approval or consent.

Dr Wael Agur, leading Uro-gynaecologist also resigned due to his concerns for patient safety.

The English Report also came under attack by Mesh Campaigners and Survivors because the six Patient Representatives felt that they were not listened to at all.

Both of these Review Reports are seen as flawed by Mesh Campaigners and by their supporters, so we find it surprising that these reports are being used as a guide by the Welsh Working Group.

Nicola and I received the Agenda for the first Task and Finish Group Meeting on the 13th October, just four days ago. We feel that there has been little time to prepare ourselves for this. Please remember that we are both Mesh injured patients, we are both struggling and [*details of their medical history have been redacted*].

We both feel that to enter into this group without a full understanding of its Agenda would be wrong. We also believe that for us it would be morally wrong to be working on 'Patient Consent' for operations that we are opposed to, rather than 'Patient Safety' and we feel that patients cannot be protected until there is a call for a suspension on the use of Surgical Mesh, pending a full investigation.

You are all probably aware that there is a Parliamentary Debate on the Safety of Surgical Mesh Implants also taking place on the 18th October at Westminster. Globally, Mesh Survivors are hoping to hear calls for a suspension in the use of mesh in England, in-line with Scotland (since 2014)

Yesterday, we heard that Bristol Surgeon Anthony Dixon was being investigated by the NHS because 16 of his former patients have taken out a legal class action against him. The newspapers were full of this and there was also a television programme last night.

I was referred to Anthony Dixon three years ago by my Cardiff Consultant. Thankfully my Bristol Mesh Injured colleagues alerted me and saved me from more mesh misery.

Whilst the use of Mesh continues unheeded, this media hue and cry, and these legal class-actions are going to be the future of Mesh. It is already being described in the media as this generation's 'Thalidomide Scandal'...

The numbers of Mesh injured patients in Wales may be seen to be quite low, but until mandatory reporting of adverse events by Consultants, GPs and the prompting of Patients to also report adverse events, no true figures will ever be established.

Do we, in Wales, continue to use Surgical Mesh Implants until the numbers rise high enough to then 'warrant' a Government investigation in Wales?

How many lives need to be destroyed and families torn apart before this scandal is taken seriously?

So, after saying all of that, Nicola and I feel that we will not be pressured into this first meeting. We would like to see the full Terms of Reference and the Minutes of this weeks meeting before we move forward.

In the meantime we are already collecting and preparing a folder of 'Patient Experience of Adverse Events' and gathering useful information, so that the voices of Mesh injured Patients - Hernia and Pelvic can be heard.

We also ask that a Hernia Mesh injured Patient Representative be invited onboard.

Welsh Mesh Survivors, once again, call upon our CMO Dr Frank Atherton to suspend the use of Surgical Mesh Implants pending a full investigation and long-term follow up of Mesh implanted patients

Yours Sincerely

Jemima Williams and Nicola Hobbs

**********

Welsh Mesh Survivors are very pleased that all of our hard work has led to the Welsh Cabinet Secretary for Health Vaughan Gething setting aside £1,000,000 a year, not only in order to make a way forward in treating those already injured by Mesh, but also to set up safer pelvic health care pathways for future patients.

May 8th 2018 Plenary Meeting - Vaughan Gething AM 15:21:48

Cabinet Secretary for Health and Social Services

Diolch, Dirprwy Lywydd. On Friday, I published the report of the task and finish group that I established to review the use of vaginal synthetic mesh tape and sheets in the treatment of stress urinary incontinence and pelvic organ prolapse. This report provides a comprehensive account of the use of mesh in Wales and the problems associated with it. Importantly, it makes recommendations on what action we should now take to make necessary and rapid improvement. I thank the members of the task and finish group for the work they have undertaken. I do want to acknowledge the courage and commitment of those women who have worked tirelessly to highlight this issue. Whilst, understandably, they chose not to participate directly in the group's work, the evidence that they provided has informed the findings and recommendations—and, of course, I've previously reported meeting a group of mesh survivors themselves. 183

All reviews to date have shown how difficult it has been to have a reliable assessment of the scale of the problem that can be linked to the use of vaginal mesh. However, what is clear is that while many women may have benefited from such treatment, some women have suffered serious and life-changing complications as a consequence. The report reaffirms this and provides clear advice on what needs to be done to support those who are living with the debilitating effects of mesh complications. It is also clear about the need to improve our approach to the management of pelvic health problems going forward.184

There are clear limitations with the adequacy of our data to understand the level of complications. The report explains why this is the case and proposes some short term and longer term solutions to address this. However, what is clear from the data presented is the sharp downward trend in the number of patients who have had mesh procedures in Wales over past 10 years. During the course of this review, the National Institute for Health and Care Excellence published new guidance, in December 2017, stating very clearly that transvaginal mesh repair for vaginal wall prolapse should only be used in the context of research. I note the task and finish group welcomed this decision by NICE and had reached the same view. I, of course, expect that advice to be followed in Wales.185

The report's overall findings and recommendations fall within five key areas: the initial care pathway required to support women's pelvic health and well-being, which includes access to multidisciplinary teams of clinicians incorporating continence care, physiotherapy, pain management and, where appropriate, psychology skills; providing better information for patients to ensure they can make a fully informed and shared decision about treatment options; ensuring GPs can have direct access to specialist advice, so they can better support their patients; making significant improvements in the processes associated with data capture of both procedures undertaken and any implants used; and ensuring access to specialist support for mesh removal by developing one or more fully accredited multidisciplinary specialist centres. I now want to ensure that the report's recommendations are taken forward at pace.186

What is particularly clear to me, after reading this report, is that we need to have a fundamental change in the way that the NHS supports women with pelvic health problems, moving to a focus on prevention and conservative therapies, with surgical intervention as a last resort. At the same time, we need to ensure there is early access to specialist support for those with treatment complications to prevent the worst outcomes. I am therefore establishing a ministerially directed implementation group to oversee specific areas of women's health requiring urgent attention and improvement. In the first instance, its priority will be to oversee the implementation of the recommendations from the vaginal mesh and tape review. Alongside this, I also want the group to consider any recommendations arising from the endometriosis and faecal incontinence reviews that are in progress. The mesh and tape review highlights that we can expect there to be a number of overlapping areas that need to be brought together.187

Following this initial focus, I will take advice from the chief medical officer and the chief nursing officer in determining what the group's next priorities should be. The membership of this group will need to be flexible as, although the initial focus will be on mesh and tape, the group will require appropriate representation—both professional and lay representation—from across other areas of women's health. I'm pleased that Tracy Myhill, the chief executive of Abertawe Bro Morgannwg university health board, has kindly agreed to chair the group.188

I've made funding of up to £1 million a year available to support the improvements needed. There will, of course, be much that can be done within existing resources, through service redesign and potentially the shift of services from hospitals to communities, to ensure that a community-based pelvic health and well-being pathway is put in place in each health board across Wales. This resource should help these pathways becoming the norm across Wales on a consistent basis. In the meantime, I expect all health boards to consider the report's findings and recommendations to consider what local improvements can be made immediately. Our aim must be to ensure women receive the best possible care and treatment when they present with stress urinary incontinence or pelvic organ prolapse, or any other complications as a result of existing treatment.189

I've asked my officials to set up the implementation group without delay, and I will expect regular updates on progress. It will, of course, be important for the work to be underpinned by a range of measures in order to be able to demonstrate improvements in patient outcomes and experience. The group will also need to keep its work under regular review in line with any new evidence that emerges. I have also shared the report of the task and finish group with the chairs of the Medicines and Healthcare Products Regulatory Agency and NICE, and asked that it informs their ongoing work in this area. I believe these steps provide the opportunity to have a much-needed focus on women's health and enable the NHS to tackle key areas that have long needed improvement.190

**********

I have copy/pasted the details of the first meeting with WHIG above.

My husband xxxxxxx and myself also had the pleasure of meeting with Lord James O'Shaughnessy, xxxxxxxxxxxxx and other UK Mesh Survivor Representatives, whom took part in the meeting via telephone link.

UK MESH SURVIVORS WILL REMAIN UNDIVIDED IN OUR RESOLVE TO ENSURE BETTER TREATMENT AND CARE IS GIVEN TO THE ALREADY MESH INJURED PATIENTS AND TO PREVENT INJURY TO FUTURE PATIENTS.

**********

WELSH MESH SURVIVORS WOULD LIKE TO TAKE THIS OPPORTUNITY TO ONCE AGAIN THANK BARONESS CUMBERLEGE AND THE REVIEW TEAM AND WE HOPE THAT THE OUTCOME OF THIS REVIEW WILL EVENTUALLY RESULT IN THE BANNING THE USE OF SURGICAL MESH DEVICES

YOURS FAITHFULLY

JEMIMA WILLIAMS - ON BEHALF OF WELSH MESH SURVIVORS

# Meshies United Group UK

## 1. Cover letter

F.A.O. Valerie Brasse
Mesh Review Team
Kings College London Shepherds House
Room 3.25b
London SE1 1UL

**Mesh Review Team**

Reference Mesh Review and Meshies United Group UK

Meshies United Group UK has been constantly active over the last 10 years asking for help for mesh injured women.

I have taken a Petition to 10 Downing Street January 2012 asking for help from the government. The Prime Minister at the time was David Cameron.

I have also met personally with The MHRA upon two occasions and also as a Working member of The NHS England Working Group on Mesh.

I met with David Richmond Chair at the time of The RCOG and [redacted] surgeon for talks at their headquarters Regents Park.

I have also travelled to The European Commission in Brussels to meet Jaqueline Minor Consumer Affairs Minister at the time at The European Commission.

I also travelled to [redacted] to meet with [redacted] surgeon about mesh issues.

I have protested also over the last 10 years and featured in National Newspaper article 2012 to highlight the mesh injuries issue.

These are some of the places I have been to and people I have spoken with since the year 2008 which is over a decade ago. These people all knew of the damage mesh was causing and turned a blind eye.

This operation should be banned that is what I personally think. I have dedicated 10 years of my life to this cause and I hope that this review will at least give some hope that this mesh issue of the injured is being taken seriously.

Thanking you

Yours sincerely

[redacted]

Mrs Teresa Hughes
Meshies United Group UK

## 2. Contents

Contents enclosed:

Leaflet Meshies United Group UK give out to delegates surgeons at UKCS 2012 Incontinence Conference St Georges Hall Liverpool:

Freedom of Information asked of Jeremy Hunt Health Secretary 5 July 2014 Suspension of Transvaginal Mesh (what do they Know):

Petition to have Independent Review of The UK Medicine Health Regulator for failures of duty regarding Transvaginal and Prolapse Mesh Injuries:

MHRA Response to Mrs Teresa Hughes and Mrs Ann Boni Meshies United Group presented to John Wilkinson of The MHRA UK Wednesday 25 September 2013 at The Department of Health Building London. Prior to meeting Earl Howe and Catherine Calderwood:

Leaflet on The Flawed Procedure for Transvaginal Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence:

[redacted] M.D. Leaflet on a Patient regarding mesh related pain:

**Minutes of The first NHS England working group on vaginal mesh and tape 16 July 2014: Please note that due to ill health I could not attend this meeting:**

Questions and answers asked recently to surgeons about mesh removal:

Lack of informed consent /contents discussed at NHS England First meeting 16 July 2014:

Statement read out at The NHS England Group Mesh Working Group 16 July 2014 [redacted] and Ann Boni Meshies United Group UK:

BMJ Open Research Trials of Transvaginal Mesh devices for pelvic organ prolapse: a systematic database review of The US FDA approval process:

[redacted]

Letter Mrs Teresa Hughes Meshies United Group UK formed the year 2008

## 3. Leaflets Meshies United Group UK UKCS 2012 Conference

18 April 2012 Leaflet Meshies United Group UK

This leaflet below was given out to the delegates attending the 19th Annual Scientific Meeting UKCS 2012 Incontinence Conference at Liverpool St. Georges Hall. The figures for England were also attached when I went to Liverpool on the 18 April 2012 to protest outside.

I was approached by 3 of the organisers of this event in Liverpool and was treated with the utmost respect and we had talks about why I was there and why I had given the leaflet out to delegates and the way forward.

It was a very prosperous day in reaching out to delegates about our plight as sufferers of this mesh medical device.

---

**Ban Transvaginal Mesh Operations in Women**

Suffering in Silence and Maimed for Life

Transvaginal Mesh is not inert in the human body especially in the bladder area. Thousands of women in The United Kingdom and Worldwide are suffering serious complications.

Changes need to be made to the regulation of these products especially in Europe where they are passed as safe with a kite mark to put them onto the worldwide market.

We are suffering in silence and we have nowhere to go and we need help from competent surgeons. According to the statistics enclosed from Hospital Episodes this is just for England alone and excludes Ireland Scotland and Wales.

Between 2006 and 2011 a Total of 64,311 tapes have been inserted into women for stress urinary incontinence.

Surgeons who are doing the mesh removal operations which so far is a total of 2,659 in England alone these mesh removals have not been recorded with The Medicine Health Regulator in The United Kingdom as adverse incidents because surgeons are allowed to volunteer an adverse incident to The MHRA UK.

The total of adverse incidents should read nearly 3,000 mesh removals. The voluntary reporting by surgeons who do mesh removal needs to be changed by law.

Many women have lost their jobs their homes and some have lost their husband or partner. Their sex lives have changed forever in fact many women do not have a sex life because of the erosion and damage caused by the mesh.

Men have also been affected because the mesh has cut their private parts. Some women have died and others wish they were dead because of the amount of pain they are in.

General Practitioners do not know how to deal with this situation and many women who contact their GP for help are being referred to a mental health team because their lives have fallen apart.

Would you like to be maimed for life by this barbaric operation?

Teresa Hughes

Owner and Founder www.meshiesunitedgroup.co.uk

### 4. Freedom of Information asked of Jeremy Hunt Health Secretary 5 July 2014

Available online here:

https://www.whatdotheyknow.com/request/suspensionof_transvaginalmesh

### 5. Petition to have Independent Review of The UK Medicine Health Regulator

Available online here:

https://www.gopetition.com/petitions/to-have-an-independent-review-of-the-uk-medicine-health-regulator-for-failures-of-duty-regarding-transvaginal-and-prolapse-mesh-injuries.html

### 6. Response to questions presented by Meshies United Group UK to MHRA

The Review does not currently have permission to publish this.

## 7. Leaflet on the Flawed Procedure for Transvaginal Mesh

# THE FLAWED PROCEDURE FOR TRANSVAGINAL MESH FOR PELVIC ORGAN PROLAPSE AND STRESS URINARY INCONTINENCE

Large steel needles resembling butchers hooks (trocars which lead the way for the mesh) are blindly inserted into the retropubic or obturator space. This may, and often does cause potential nerve, organ or tissue damage.

Transvaginal mesh implants contradict core principles of surgery. The vagina is a clean-contaminated surgical field, which means that unlike the skin of the abdomen, it can't be fully disinfected before surgery. Infection is a risk for any type of implantable device. Passing a mesh through a contaminated field is an invitation to infection. Transvaginal mesh violates the Golden Rule of Surgery: "You shall never implant a synthetic object into anyone's body, anywhere, if it's contaminated. This procedure contravenes what every surgeon is taught in medical school and beyond.

The vagina may contain bacteria and organisms such as: E coli, Strep B, Staphylococcus, Lactobacillus and Candida Albicans to name but a few. Whilst we appreciate that they live there out of habit-commensals, they have no place beyond the vaginal canal. Infection will inevitably happen if a porous mesh is passed through the vagina into the pelvic cavity. This is demonstrated by the links I have provided on explanted mesh.

**Polypropylene implants are not inert**
http://journals.lww.com/greenjournal/Abstract/2010/10000/Polypropylene_Vaginal_Mesh_Grafts_in_Gynecology.24.aspx

**Thank you to TVT Info for the following article**
**https://tvtinfo.wordpress.com/2012/10/14/10-good-reasons-to-avoid-mesh/**

**Vaginal mesh for prolapse: a randomized controlled trial.**

**http://www.ncbi.nlm.nih.gov/pubmed/20664388**

**http://www.europeanurology.com/article/S0302-2838%2812%2900235-7/fulltext/tension-free-vaginal-tape-and-beyond-our-challenges-and-the-future-of-anti-incontinence-therapy**

**Polypropylene mesh in vaginal surgery Dr Margolis**
http://www.bapelvicsurgery.com/Polypropylene%20Mesh%20in%20Vaginal%20Surgery%20A%20Risk%20Analysis.pdf

**Ethicon warning not to place devices in a contaminated site for the Gynecare Interceed. Pity they did not warn that the vagina is a contaminated site.**

**http://www.pelvichealthsolutions.com/gynecare-interceed**

PLEASE NOTE THAT ENGLISH IS NOT [redacted] FIRST LANGUAGE

Email from [redacted]

to present to NHS England Working Group on Mesh and Tape

on 3rd November 2014

On Tuesday, 15 July 2014, 14:36, [redacted] M.D." [redacted] wrote:

I have removed now more than 1000 mesh for complications.

We can cure or improve 75-80% after mesh removal but 20% of the patient may be permanent disabled.

Mesh is inserted to improve anatomical results at the cost of 5-20% complications (minor and major). Quality of life is what counts. Traditional surgery (no mesh) compared with the use of mesh gives the same results of improving quality of life and bother scores.

We are looking at why is happening that a few years later patient develop this complications.

The vagina has bacteria even after the surgical scrub at the time of surgery. The mesh is inserted through a contaminated area. The mesh is

infected at the time of the implant creating a biofim ( a colony of bacteria inside a protein envelope). Antibiotic cannot cure mesh infection. Bacteria can be dormant in the mesh for a long time but can be activating itself, expand and create the late complications of mesh.

## 8. MD Letter regarding mesh pain

May 21, 2018

Regarding: A patient suffering mesh related pain

To whom it may concern,

The purpose of this letter is to inform doctors, employers and loved ones of patients suffering a condition broadly known as mesh related chronic pain of some essential facts that will help you to understand what is going on with your patient, employee or loved one. I am a board certified general surgeon who specializes in the care of patients with hernia mesh problems. I am frequently asked by my patients to write a letter like this because they have trouble making other people understand what they are going through. So I write this as an open letter to be used by any patient suffering mesh pain.

Patients with groin or abdominal pain lasting more than three months after mesh hernia surgery nine times out of ten have mesh related pain. This essential fact is not widely appreciated by the medical community. The medical literature about mesh related pain is sparse and confusing. But the problem is huge and for the individual patient with mesh pain can be devastating.

20% of patients who have mesh hernia surgery develop chronic pain. 5% develop pain so severe that it seriously adversely affects the quality of their lives. Effective treatment options are extremely limited. Most patients never get better and suffer social isolation, career ruin and financial loss in addition to their pain.

Typically patients with mesh pain will go back to their surgeons with their persistent complaints of pain. The surgeon will examine them and find nothing wrong. The surgeon will order some medical imaging tests and find nothing wrong. The surgeon realizing he has nothing to offer the patient will then refer them to a pain management specialist.

Mesh related pain is not due to surgical technical error or failure of the device to remain in proper position. Imaging studies are not helpful in making the diagnosis. There are no objective tests that will make the diagnosis. The diagnosis is a clinical diagnosis based on the patient's subjective complaints and the patient's history. A lack of objective findings can be very troubling for a doctor who does not have a lot of experience taking care of these patients.

The standard protocol for treating patients with mesh related pain includes narcotic pain medication, nerve stabilizing medications, nerve injections, nerve destruction, steroid injection of scar and to the extreme of spinal cord stimulators. None of these provide lasting relief and for many patients the side effects are intolerable. Mesh removal can help some patients but there are only a few surgeons in the world who have experience and good results. The decision to remove mesh should not be taken lightly.

Many mesh patients also relate symptoms other than pain to their mesh such as fatigue, weight loss, headaches, abdominal pain, skin rash, body aches, prostatitis, cystitis and other autoimmune like symptoms. These symptoms should not be dismissed out of hand. Mesh causes chronic inflammation which cause the production and systemic release of nerve growth factor and various other neurotrophs and tumor necrosis alfa and various other immune mediators.

Patients with chronic severe mesh pain develop a condition called central pain sensitization (CPS). Clinical features of CPS include allodynia, hyperalgesia and widening of the pain which can be very confusing to the patient and their doctor. In particular widening of the pain field creates a contradictory picture because it is a central nervous system phenomenon. The distribution of the pain fields does not correlate with peripheral pain pathways. Patients and doctors tend to think in terms of peripheral processes. Central pain sensitization is responsible for other well-known clinical pain syndromes such as phantom limb pain and complex regional pain syndrome (CRPS). Central pain sensitization is a prominent component of chronic hernia mesh pain.

Wasting time beyond three months doing nothing or doing ineffective treatments and useless imaging hoping the pain will go away is not advisable. The more time that goes by the more that central pain sensitization becomes instantiated and the less likely that the patient will be cured of their pain.

The last point that I would like to make for doctors specifically is that exploratory surgery is a bad idea. The diagnosis of mesh pain is not based on gross pathological/anatomical findings. Microscopic pathological examination will reveal chronic inflammation, neo-nerve sprouting and invasion of other organs and structures. Chronic inflammation is found in all mesh explant specimens and alone is sufficient pathology to cause pain. Operate if you clearly have a hernia recurrence. But not just because you suspect one. Operate if you have made the decision to take the mesh out. If you do though, take it all out and do not replace it.

For the friends, family and employers of mesh pain patients please understand that their pain is real and they are suffering a condition that there is not much help for but the greatest loss that they can suffer is the loss of your support.

Anyone who needs more information or advice may reach me at [redacted]

Sincerely,

[redacted]

## 9. Minutes of the Working Group on Vaginal Mesh and Tape 16th July 2014

The Review does not currently have permission to publish this online.

## 10. Q&A surgeons mesh removal

[redacted]

- Do you remove the TVT device in its entirety or partially?
    - Depending on clinical situation, we can remove partially or completely
- Which is your preferred method of removal surgery i.e. do you remove the device via the vagina, abdominally or do you utilise a laparoscope?
    - This depends on clinical indication and type of tape. majority are vaginal but some are laparoscopic and open suprapubic
- Do you remove Obturator mesh tapes in their entirety or partially?
    - Depends on indication, but able to do both. Rare to remove in entirety
- Again, which is your preferred method of removal surgery - via the vagina, abdominally or do you utilise a laparoscope vaginally?
    - It would only be appropriate to go abdominally or laparoscopically if tape in incorrect position
- Can you remove Prolapse mesh in its entirety or partially?
    - Both
- Again, which is you preferred method of removal surgery via the vagina, abdominally or do you utilise a laparoscope?
    - Depends on type of mesh. Vaginal meshes - vaginal removal. Sacrocolpopexy/Hysteropexy or Rectopexy meshes usually laparoscopic but sometimes open surgery needed.
- It states in the N.I.C.E Guideline that surgeons are only considered proficient in installing mesh if they complete 20 procedures per year. So the same would follow for mesh explants. Therefore, do you remove more than 20 or more mesh implants per annum?
    - Yes
- If you don't remove more that 20 mesh implants per annum, how many are you removing?
- Can you remove as much of the mesh implant as is safe to do so in one surgery?
    - Yes - will depend on discussion with patient beforehand
- What do you perceive is the risk of nerve damage to the woman percentage wise for these removal procedures?
    - I can't give a figure for this without a specific example. The risk of nerve injury is probably highest in complete Obturator tape removal.

- Do you use translabial ultrasound to map out the mesh implant particularly for a secondary removal?
    - Yes, particularly for tapes
- How long in weeks or months do you expect the patient's recovery to take, approximately?
    - Dependant on how extensive surgery is and route of surgery
- Do you send removed mesh to the laboratory for histology?
    - We are happy to do this.
- Can you arrange to have the mesh preserved for legal purposes?
    - Yes, usually the patient's solicitor makes arrangements for mesh collection.
- Will you report the patient's mesh complication as an adverse incident to the MHRA?
    - Yes, we have been reporting since 2012
- Do you remove mesh both privately and on the NHS?
    - This may vary between surgeons. In general, major mesh removals are performed in NHS hospital
- Can you facilitate continence after removal of mesh by means of autologous sling or a Burch Colposuspension?
    - Yes, both are available
- Can patients have an annual check up with you if any mesh remains?
    - Yes, if they wish to
- Has the mesh removals you have done so far been deemed a success by your patients?
    - Majority satisfied. A few patients have found pain has not improved.
- How many mesh implants have you removed in your career so far, approximately?
    - I don't have information to hand for all surgeons. The Warrell unit consultants are all subspecialists and have been consultants for approx 9-10 years.
- How long is your waiting list for mesh removal from first consultation to removal date approximately?
    - I don't have accurate information for this. Surgical waiting times are 2-4 months. We perform major mesh removals as joint cases with either 2 gynaecologists or with a colorectal surgeon - this needs special organisation and waiting times vary. Patients may also need investigation such as ultrasound, MR scan or assessment by pain consultant, which can add to waiting time.

[redacted]

[redacted]

[redacted]

[redacted]

- Do you remove the TVT device in its entirety or partially?
    - Both
- Which is your preferred method of removal surgery I.e. do you remove the device via the vagina, abdominally or do you utilise a laparoscope?
    - Vaginal and abdominal, no laparoscopic, as some of the mesh cannot be seen and has to be done by feel
- Do you remove Obturator mesh tapes in their entirety or partially?
    - Both, depends on symptoms and have an orthopaedic surgeon available, if we have to remove in entirety
- Again, which is you preferred method of removal surgery via the vagina, abdominally or do you utilise a laparoscope?
    - Same as above
- Can you remove Prolapse mesh in its entirety or partially?
    - Depends on the mesh type and insertion
- Again, which is you preferred method of removal surgery via the vagina, abdominally or do you utilise a laparoscope?
    - As above
- It states in the N.I.C.E Guideline that surgeons are only considered proficient in installing mesh if they complete 20 procedures per year. So the same would follow for mesh explants. Therefore do you remove more than 20 or more mesh implants per annum?
    - I disagree, as the volume of mesh removed does not equate to the volume inserted. Proportion of removed mesh is far less. NICE also state that you can insert at least 5 meshes a year, but within the context of an MDT.

- If you don't remove more that 20 mesh implants per annum, how many are you removing?
    - I remove at least 10 meshes a year, within the context of an MDT
- Can you remove as much of the mesh implant as is safe to do so in one surgery?
    - Yes
- What do you perceive is the risk of nerve damage to the woman percentage wise for these removal procedures? Which nerve?
    - Depends on type of mesh, the amount of scar tissue, and where the mesh is, but I would say it is low, but I always warn patients it may happen.
- Do you use translabial ultrasound to map out the mesh implant particularly for a secondary removal?
    - No
- How long in weeks or months do you expect the patients recovery to take approximately?
    - Depending on whether it is partial or total and what type of mesh (incontinence or prolapse) and approach (vaginal or abdominal) is used. Could be weeks, but not usually more than 3-6 months.
- Do you send removed mesh to the laboratory for histology?
    - No I send for microscopy, and culture as most are eroded meshes that may be infected
- Can you arrange to have the mesh preserved for legal purposes?
    - Not looked into it
- Will you report the patient's mesh complication as an adverse incident to the MHRA?
    - Yes
- Do you remove mesh both privately and on the NHS?
- Yes
- Can you facilitate continence after removal of mesh by means of autologous sling or a Burch Colposuspension?
    - Yes
- Can patients have an annual check up with you if any mesh remains?
    - Followed up as per national guidelines. If clinically well, then not followed up.
- Have the mesh removals you have done so far been deemed a success by you patients?
    - Yes

- How many mesh implants have you removed in your career so far, approximately?
    - 50
- How long is your waiting list for mesh removal from first consultation to removal date approximately?
    - Variable depending on symptoms, but usually within 3 months.

[redacted]

[redacted]

- Do you remove the TVT device in its entirety or partially?
    - ENTIRE TVT, IF POSSIBLE
- Which is your preferred method of removal surgery I.e. do you remove the device via the vagina, abdominally or do you utilise a laproscope?
    - COMBINED ABDOMINAL (USUALLY LAP) AND VAGINAL APPROACHES
- Do you remove obturator mesh tapes in their entirety or partially?
    - ENTIRE TOT IF POSSIBLE
- Again which is you preferred method of removal surgery via the vagina, abdominally or do you utilise a laproscope?
    - VAGINALLY AND IF NECESSARY A SEPARATE GROIN INCISION(S)
- Can you remove Prolapse mesh in its entirety or partially?
    - I DO NOT DO THIS SURGERY BUT THE LEAD GYNAECOLOGIST, [redacted], DOES ALL MESH REMOVAL CASES WITH ME – WE HAVE NOT HAD A POP MESH THROUGH AS YET
- Again, which is you preferred method of removal surgery via the vagina, abdominally or do you utilise a laproscope?
    - ABDOMINAL LIKELY BUT SEE ABOVE
- Do you remove mesh for Rectopexy and Sacrocolpopexy devices in their entirety or partially? By which route are these meshes removed? Is organ removal likely by removing these meshes and which organs could be compromised or have to be removed?
    - NOT DONE ANY OF THESE CASES – WOULD NEED GYNAE AND COLORECTAL HELP IF WE WERE TO GET SUCH A CASE
- It states in the N.I.C.E Guideline that surgeons are only considered proficient in installing mesh if they complete 20 procedures per year. So the same would follow for mesh explants. Therefore, do you remove more than 20 or more mesh implants per annum?
    - PROBABLY NOT 20 PER YEAR – HOWEVER THE REQUIRED SKILLS ARE TRANSFERRABLE FROM OTHER PROCEDURES, SUCH AS VESICO-VAGINAL FISTULA / URETHRAL DIVERTICULUM SURGERY – ALL CASES IN [redacted] ARE DONE JOINTLY BY ME AND A GYNAECOLOGIST AND BETWEEN US WE BRING SUFFICIENT SKILLS – WE BOTH HAVE A VAST EXPERIENCE OF VAGINAL AND RECONSTRUCTIVE SURGERY. I WOULD POINT OUT THAT THE FIGURE OF 20 CASES PROPOSED BY NICE IS NOT SUPPORTED BY ANY CLINICAL EVIDENCE – INDEED THE BAUS SUI AUDIT (ABOUT TO PUBLISH) DID NOT SHOW ANY DIFFERENCE IN OUTCOMES BETWEEN HIGH AND LOW VOLUME SURGEONS. PAUL HILTON'S PREVIOUS WORK RE VESICO

VAGINAL FISTUAL SURGERY SHOWED THAT 3 CASES PER YEAR WAS A REASONABLE DISCRIMINATOR.

- If you don't remove more that 20 mesh implants per annum how many are you removing?
  - WE HAVE ONE JOINT LIST PER MONTH AND THE OCCASIONAL EXTRA LIST SO 10-15 CASES PER YEAR. THE [redacted] MODEL IS TO DO THESE CASES WITH A UROLOGIST (ME) AND A GYNAECOLOGIST [redacted] PRESENT AS THEY ARE NOT ALWAYS PREDICTABLE.
- Can you remove as much of the mesh implant as is safe to do so in one surgery?
  - YES
- What do you perceive is the risk of nerve damage to the woman percentage wise for these removal procedures.?
  - HIGH – WE CONSENT FOR FAILURE TO IMPROVE PAIN AND FOR LOWER URINARY TRACT DYSFUNCTION – BOTH OF WHICH CAN OCCUR BECAUSE OF NERVE DAMAGE.
- Do you use translabial ultrasound to map out the mesh implant particularly for a secondary removal?
  - NO – THERE IS NO EVIDENCE PUBLISHED TO SUPPORT THE USE OF TRANS-LABIAL USS – I WOULD ENCOURAGE THE ENTHUSIASTS OF THIS TECHNIQUE TO PUBLISH THEIR RESULTS – THE USE OF IMAGING PRE-MESH REMOVAL IS AN EVIDENCE GAP THAT REPRESENTS A RESEARCH PRIORITY IN MY OPINION – I FIND MRI USEFUL TO RULE OUT PERI-MESH ABSCESSES ETC BUT ITS PRETTY POOR FOR LOCATING MESH. I HAVE NOT AS YET HAD ANY PROBLEMS LOCATING AND FOLLOWING THE MESH DURING SURGERY SO NOT SURE WHAT TRANS LABIAL USS WOULD ADD.
- How long in weeks or months do you expect the patients recovery to take approximately?
  - EACH CASE IS INDIVIDUAL
- Do you send removed mesh to the laboratory for histology?
  - NOT ROUTINELY – WE DO SEND TO MICROBIOLOGY FOR CULTURE WHICH IS MORE USEFUL IN MY OPINION
- Can you arrange to have the mesh preserved for legal purposes?
  - NOT SURE – WE NEVER HAVE
- Will you report the patient's mesh complication as an adverse incident to the MHRA?
  - YES ALWAYS
- Do you remove mesh both privately and on the NHS?
  - I DON'T DO PRIVATE WORK – IM A BIT OF A SOCIALIST!
- Can you facilitate continence after removal of mesh by means of a fascial sling or a Burch Colposuspension?
  - YES, BUT WE ALSO CAN DO IT AS PART OF THE MESH REMOVAL SURGERY – DEPENDS ON WHAT THE PATIENT WANTS
- Can patients have an annual check up with you if any mesh remains?
  - YES
- Has the mesh removals you have done so far been deemed a success by you patients?

- INITIALLY YES BUT I WOULD SAY IT'S A BIT EARLY TO TELL

- How many mesh implants have you removed in your career so far, approximately?
  - NOT SURE – NOT MORE THAN 15 – HOWEVER, THERE ARE QUITE A FEW COMING THROUGH, SO THIS FIGURE WILL INCREASE
- How long is your waiting list for mesh removal from first consultation to removal date approximately?
  - NOT SURE – DOING ONE TODAY WHO WAS REFERRED IN LATE 2017, BUT NEEDED FURTHER INVESTIGATION - ALL OF THE MESH REMOVAL CASES ARE REFERRED TO [redacted] WHO LEADS THE MESH REMOVAL SERVICE IN [redacted] AND MY ROLE IS LIMITED TO CASE REVIEW AND MDT DISCUSSION [redacted] AND THEN JOINTLY PERFORMING THE SURGERY WITH [redacted]

## 11. Lack of informed consent document

# LACK OF INFORMED CONSENT

Informed Consent

*NHS definition of informed consent:*
*For consent to be valid it must be voluntary and informed and the person consenting must have the capacity to make the decision.*

Transvaginal Mesh Victims were not informed and our consent was not valid. We were not warned of known risks and complications associated with Polypropylene Mesh Implants.

We weren't told that surgery is sometimes not necessary or that several non-mesh alternatives are available.

We were told that these devices had an 85% success rate we weren't told what happened to the other 15%.

The success rates are optimistic, to say the least. And what constitutes a successful implant anyway? A surgeon manages to place the device without puncturing our bladder? Or that it stops us leaking urine – perhaps because we may be unable to void after surgery anyway?

We weren't told that devices were permanent and notoriously difficult and dangerous to remove.., safely.

We weren't told that we'd struggle to get help if we suffered an adverse reaction because there are only a few surgeons in the U.K. experienced in mesh removal. Ladies have had great difficulty in obtaining out of area referrals and some G.P's and hospitals refuse to sanction these referrals

We weren't warned that mesh can erode into our bladder, urethra,

vagina or bowel and surgeons have likened it to "Removing chewing gum from hair". This can happen from day one of implant until 10 or more years later. There are no long term, quality, robust clinical trials so no one knows the actual prognosis.

We weren't told that mesh can shrink and contract between 30 - 50% just 4 weeks after implant - which has been known since 1998 - tightening & shredding as it embeds into delicate tissue.

We weren't told that the nice soft mesh described to us hardens or that the serrated edges of these devices can cut through our organs like a grater through cheese.

We weren't told that we may suffer loss of intimacy with our partners due to pain or a shortened and scarred vagina caused by multiple surgeries to remove the offending material. We weren't told that during intercourse our partner's genitals could be cut to shreds - "penis fly trap", as one consultant gynecologist so crudely put it.

We weren't told of the risk of nerve damage and the very real possibility that this could be permanent and debilitating.

We weren't told that our stress urinary incontinence could actually worsen or that we may develop urge urinary incontinence and have to wear nappies 24/7.

We weren't told that we could experience Foreign Body Reaction, excruciating pain and constant urinary tract infections as our bodies struggle to reject this material.

We weren't told that we may need to self-catheterise long term or that mesh fibres in our urine are commonplace.

We weren't told that mesh can degrade and migrate around our bodies or that a higher than average amount of women with

polypropylene mesh go on to develop auto immune diseases.

We weren't told that a rep from the mesh manufacturer may be present during our operation, watching and supervising.

One surgeon stated that they can perform 100 Burch Colposuspension operations or 600 Transvaginal mesh implants per year to treat stress urinary incontinence — both have a 20% (that is a 1 in 5 failure rate). They said that mesh, the quicker, cheaper option made more sense — how wrong and misguided. This is a false economy when compared to the cost of multiple surgeries, expensive scans, physiotherapy and medications and more importantly, the cost of human suffering.

When a Burch Colposuspension fails — it stops working you are in effect back to square one — a leaky bladder. When Transvaginal mesh fails it causes devastating life long injuries.

Our lives and that of our families have been destroyed, we have lost our health, marriages and relationships have fallen apart, jobs have been lost, houses have been repossessed or in some cases a house move or the need to have it specially adapted to accommodate our disabilities has been necessary. We have lost our dignity but one thing we have not lost is our marbles, as some surgeons would have us believe. We are repeatedly told we are unique and that our pain is psychological — neither is true.

Hamoodi I1, Tyagi V1, Abdulrahman O1, Guerrero K1, Perera M1
*1. NHS Greater Glasgow and Clyde*
**CONSENTING FOR TAPE PROCEDURES**
http://www.ics.org/Abstracts/Publish/106/000011.pdf

## 12. Statement read at the Working Group on Mesh - 16th July 2014

# [redacted] AND [redacted] STATEMENT AT THE ENGLISH GROUP WORKING PARTY MEETING HELD CONVENED TO DISCUSS THE SERIOUS CONCERNS ON TRANSVAGINAL MESH HELD 16TH JULY 2014

Thank you for this opportunity to be a part of the working party addressing concerns about pelvic mesh procedures. We are obviously doing this in our own time which demonstrates how strongly we feel about the damage these procedures have caused and are continuing to cause in human terms. We put ourselves forward to represent all those who have been failed by a system which has allowed pelvic mesh products onto the market without adequate robust trialling, testing and data to prove short and long term safety. As patient representatives we welcome being involved despite the extremely short notice for us to adequately prepare with a lack of agenda until 5.40pm Monday 14th.

We are however extremely well informed having been immersed in the world of mesh since our own implant failures. To begin with it was a desperate search on the internet for answers which were not being provided by doctors, it was then discovering that we were not the only one, but one of many thousands worldwide who have unwittingly found themselves injured and disabled by a procedure that was supposed to be minimally invasive and enhance the quality of life for those with SUI or POP.

We have had to become our own advocates spending hours searching for doctors who can safely remove mesh when told by our own that they are unable to do so. Searching for information about the composition of the mesh material which appears to be causing severe foreign body reaction, erosion, auto immune problems, chronic inflammation, infection, new bladder problems, nerve damage, dyspareunia and pain in many patients. We have read and analysed medical papers and documents and supported an ever increasing community of mesh injured women desperate for information and understanding.

Mesh injured patients have been failed by a product which we were told was the Gold Standard treatment for SUI and an effective new treatment for POP and yet we have been unable to find evidence that the procedures have long term outcomes which are any better than those available before the introduction of mesh. The evidence we can find however is that when mesh fails it is difficult if not impossible to fully remove and can seriously damage a patient for life.

The MHRA have duty to protect the public from harm and they have failed to do so.

Women have not been given the full known facts about polypropylene mesh implants and therefore have not given fully informed consent. As patients supporting other patients we hear same story from women over and over again:

- Women suffering from unexpected debilitating complications, not always aware to begin with that it is the mesh causing them and then finding that GPs do not have an understanding or the knowledge of who to refer them to.
- Women facing the risks of further painful surgeries, slow recoveries, prolonged absences from work and no guarantee of full removal or full restoration to health.
- Women losing their marriages, independence, homes, financial security the basic right to enjoy life.
- The frustration for no one taking responsibility for the damage being done and the lives being wrecked. Everyone being referred back to the MHRA who say they recognise the concerns, but continue to refer to the flawed York report which they say was based on literature available on adverse event rates!
- The refrain of *The Benefits Outweigh The Risks* certainly isn't true for all the women we are representing today. The people whose

health have been endangered or compromised by the *risk* element in that statement are real people, wives, mothers, grandmothers, sisters, daughters - are their lives not as important as those who supposedly benefit?

We are continually met with refusal of surgeons to see the devastation and harm caused by mesh implants despite plenty of evidence out there, namely:

- The ever increasing number of worldwide online support groups, TVTinfo support group alone has had 45,000 views and has only been in existence since 2012.
- The huge number of litigation cases, at the last count 75,000 against mesh manufacturers in the USA with one company now proposing to settle thousands of cases costing in excess of eight million dollars.
- Over 600 ACC (Country's Accident Compensation Corporation) mesh compensation claims in New Zealand since 2008.
- The Scottish petition and campaign by mesh sufferers which resulted in Alex Neil taking the correct action. To quote his words - *No one should suffer the level of suffering these women have.*
- Johnson and Johnson's Ethicon have already withdrawn some of their mesh products and are currently under investigation in ten US states after a judge ruled that the company destroyed hundreds if not thousands of pages of documents requested as part of the discovery process for litigation.
- Respected experts including [redacted] and [redacted] in the USA and [redacted] here in London have seen and continue to see the devastation mesh is causing and yet are still being largely ignored by mesh proponents. Doctors have to stop listening to the marketing pitch of manufacturers and start looking at the hard evidence that plastic polypropylene mesh doesn't belong in the female pelvic area and should never be implanted through an area of the body which is not sterile.

- I now pass you to [redacted] to sum up.

We are requesting that the use of pelvic mesh products for SUI and POP be suspended immediately across the UK pending a full and independent review involving patient groups at every step. This is to protect women until proper evaluation of the safety of these devices can be carried out. We believe it would be negligent of those present in today's meeting not to act on this request knowing the following:

1. There are no quality, robust clinical trials or evidence to support the statement that the benefits outweigh the risks.

2. There is gross underreporting by clinicians of adverse incidents to the MHRA because they are not compelled to do so as this is not mandatory.

3. There is no National Register to record, monitor and track data therefore complication rates are largely unknown. There is no collection of post-market data by an independent body

4. Very few patients are given fully informed consent and consent is not uniform throughout all Health Authorities. Furthermore, [redacted] the MHRA stated at a meeting on 19th July 2012 ***"without accurate data consent cannot be truly informed"***

In summation, there is a phenomenal amount of missing data so no one knows the actual scale of this mesh scandal. We believe vaginal mesh is a flawed product, a flawed procedure and experimental with women being used unknowingly as guinea pigs.

Until the safety of this device has been proven, it is an act of negligence to continue to allow these devices to be implanted. Until such time that robust data and evidence can prove long term safety and good outcomes, with success based on low *morbidity* not just anatomical results, and until such time doctors can be identified as skilled in removing mesh safely, its use should be considered high risk and

therefore not appropriate for routine surgery. Women are not likely to die from SUI or POP. But they are being harmed right now by an avoidable device and an avoidable technique.

## 13. Heneghan et al (2017) Trials of transvaginal mesh devices for pelvic organ prolapse: a systematic database review of the US FDA approval process.

Article:

Heneghan CJ, Goldacre B, Onakpoya I, et al. (2017) Trials of transvaginal mesh devices for pelvic organ prolapse: a systematic database review of the US FDA approval process BMJ Open 7:e017125. doi: 10.1136/bmjopen-2017-017125

## 14. Item not included

In line with Anonymity and Redaction Framework