

## **PE1517/RR**

Kath Sansom submission of 24 July 2017

I write on behalf of campaign group Sling The Mesh:

On July 18, 2017 we held a lobby at Parliament into the mesh implant scandal. Around 80 women and their families attended from across the UK including people who came from Scotland.

Key Points:

- \* Owen Smith to launch APPG into mesh in September.
- \* Debate will be tabled in Sept/Oct
- \* Vaginal mesh is the only blind procedure we know of - think: trying to fix fan belt on car without lifting bonnet. It uses large hooks and guess work in an area rich in nerves and where not every woman's anatomy is same due to childbirth and different vaginal tilts – the product and how it is implanted was not included in either Scottish or English final reports as a consideration.

### **Commissioning**

The NHS never planned to look into the safety of mesh as they did not commission for that. They only commissioned to look at 3 areas: Patient information leaflets, encouraging surgeons to report to databases and how to deal with women if they present with mesh problems. So it was always going to be lip service to patients right from the start.

### **Risk**

- \* NHS say risk is 1 to 3%
- \* HES data for England shows risk is 8.56%
- \* This study says risk of prolapse mesh is 10%  
[http://thelancet.com/.../ar.../PIIS0140-6736\(16\)31596-3/fulltext](http://thelancet.com/.../ar.../PIIS0140-6736(16)31596-3/fulltext)
- \* This study says risk is 12% [http://www.europeanurology.com/ar.../S0302-2838\(17\)30279-8/pdf](http://www.europeanurology.com/ar.../S0302-2838(17)30279-8/pdf)
- \* This study says risk is 15%  
<http://www.nature.com/.../jo.../v12/n9/abs/nrurol.2015.183.html...>
- \* This study says risk is 36% <https://www.ncbi.nlm.nih.gov/labs/articles/27275813/>
- \* This study says risk is 42%  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3205289/>
- \* This study says risk is 30 to 40% [http://www.europeanurology.com/ar.../S0302-2838\(12\)00095-4/pdf](http://www.europeanurology.com/ar.../S0302-2838(12)00095-4/pdf)

### **Stats – hospital episode statistics & MHRA yellow card**

It is widely documented that surgeons do not routinely report to their own society databases (BSUG and BAUS) or to the MHRA database. So figures will be woefully low.

During a discussion on 'Urological Challenges' at a BAUS conference earlier this month, captured by BAUS on a You Tube video – surgeons can be heard saying they don't report as they are "chaotic" or don't understand how to use the new system. They also are seen talking about less than 40% report.

### **No outpatient coding and short term audit**

The BAUS database only audits up to 3 months - the BSUG is short term - what surgeon monitors their patients for a long time post surgery?

They do a 6 week to 3 month check up then generally speaking it is out the door never to be seen again. Women then go back and forth to GPs or see the surgeon as an outpatient if they have problems and there are NO OUTPATIENT CODES for mesh problems so no way of capturing this data to prove how many women are suffering mesh complications. Women will be coded under eg pain or shuffled off to another department so coded under eg other gynaecology procedure or some women told their pain is eg a slipped disc. Coding will NOT capture all the women suffering. So nobody knows true scale of this disaster.

### **If less than 40% report that is 60% of data missing**

Patients wont report to the MHRA Yellow Card as never heard of it and earlier this year documents were leaked showing the MHRA wanted to take the press element out of mesh in any Yellow Card publicity "to avoid media focus on mesh" Guardian report on it here <https://www.theguardian.com/.../nhs-vaginal-mesh-implants-sca...>

### **No mandatory reporting**

At our lobby, a Urologist who sits on the English and Scottish Group Working Party into mesh said it is up to the NHS to make it mandatory for surgeons to report and to pay for the costs of that. Currently it is surgeon choice if they report their complications! Who is going to report and put themselves in the firing line for litigation! Surgeons reporting is low quality biased evidence anyway.

### **MHRA figure of 1 to 3% risk misses out loss of sex life**

That low figure only accounts for the risk of pain and erosion and doesn't use their own figure of risk for loss of sex life (dyspareunia) which is up to 13.5% SO that begs the question Why leave it out? It is a v real and distressing risk - they leave it out as it would crank up the 1 to 3%. A chart in the York Report from 2012 shows the dyspareunia risk is left out. In addition the York Report uses many short term trials or studies with conflicts of interests.

### **NHS blame surgeons**

NHS and MHRA blame surgeon skill to divert blame from the product when truth is it is a flawed product and process.

### **Flaky EU notifying bodies regulatory system**

Mesh is approved on something called Substantial Equivalence so it means a device is passed because something equivalent is already on the market - so it is passed without pre or post market studies - that is how PIP breast implant and metal hip disaster happened.

This already weak approval system will get worse under BREXIT as many devices are due to become high risk by 2020 - that will mean they need pre and post market studies. That extra level of safe guarding will be lost under BREXIT.

### **Conclusion**

The Scottish and English mesh report is a whitewash, low risk figures are a joke.

Mesh needs to stop now before more women are maimed. Even looking at figures to try to see how many women are suffering means nothing as the data does not capture anywhere near the number - from patient experience of Sling The Mesh, we have influxes of women every time there is media coverage all saying the same thing - we thought we were the only one and were just putting up with the pain as we didn't know what else to do.

Since being on the BBC Victoria Derbyshire Show in April our Sling The Mesh group has more than doubled from 1,000 up to 2,468 in just three months - members all saying the same thing - we had no idea there were others out there suffering like us as we were told we were some kind of mystery patient or told - there is nothing I can do to help you madam, you must learn to live with it.

### **Resignations**

Resignations of 4 key members; former Independent Chair Dr Lesley Wilkie, Expert Clinician Dr Wael Agur and Scottish Mesh Survivors Patient Representatives Elaine Holmes and Olive McIlroy.

Concerned that a serving NHS Medical Director Dr Tracey Gillies was appointed as Chairperson.

Like the Scottish Mesh Survivors group we feel let down and/or betrayed after the promising Interim Report and are worried that the Final Report exposes women to unnecessary harm.