From: Lorraine Evans
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Since 2009 I have received thousands of enquiries and helped hundreds of women suffering severe health problems from the TVTs/Mesh implants. Our health situation is critical and at this present time there are very few surgeons in the UK to help us. I am in regular contact with the MHRA, Department Health and with some Medical Experts to help try and bring changes to the following items:

Our campaign is to bring awareness on the following:-

1. Reclassification of TVT/Meshes medical devices from class 11 to class 111
2. To achieve a National TVT/Mesh register (the MHRA)
3. Increase awareness on reporting adverse events from the clinicians and members of the public
4. For the MHRA to issue a Public Health Notice similar to the FDA
5. Concerns with the manufacturers control bringing onto the market the medical devices without Randomized controlled trials (RCT’s) no human trial studies were done first for TVT/Meshes
6. To have multi-disciplinary teams possibly in 5 regions across the UK
7. Informed consent - the MHRA are currently raising this issue with clinicians through workshops
8. Patient safety with continued research on how the TVT’s/Meshes have affected patients health
9. Keeping up to date on current World-wide investigations.
10. To keep the much needed and valued TVT Mum campaign and support group active
DISCUSSIONS

**Surgeons**
- Surgeons need to be honest and give a fully informed consent
- 100% removal is only in the first week after this it will entail severe tissue damage and for those who have had in for years the complications are more severe, nerve, organs, etc.
- We desperately need experienced surgeons around the UK people are travelling hundreds of miles and paying thousands of pounds to private practise
- Surgeons referring patients s onto other surgeons (not reporting adverse reports)
- More help needed from the NHS – Multi-disciplinary teams urgently required

**What we want to see done within the Medical World**
- Urgent need to have a National TVT/Mesh Register and for regional multi-disciplinary teams
- Compulsory adverse reporting both from surgeons and patients, and the need to give more awareness to the public. The need to make this easier as the present system is too confusing and also some people are not internet savvy
- Public Health Notice similar to the FDA to show on the MHRA website and in the press
- Medical Device regulations to change vaginal mesh medical devices from class 11 to CLASS 111 - the meshes can cause death. 510k process predicate devices every decade plus the use of clearance instead of approval!

**The Manufacturers**

Multiple manufacturers are bringing numerous products onto the market and overtaking medical science. They have not done any long term randomised controlled human trials (RCT’s) only rat studies we were used as the guinea pigs without our consent.

**How I set up the Charity**

Lorraine put her personal life on hold to get the workload done, it has increased over the years and we provide a voluntary support help-line. We are hoping experts will come on board and help us as it’s difficult to keep the support group going whilst we are all so ill most charities have healthy people working for them!
Campaign work in the Pipeline

I recently sent a full 13 page document to the Rt Hon David Cameron MP, Prime Minister and to Andrew Lansley, CBE MP Secretary of State for Health. I have received a four page letter from the Department of Health and they answered all raised concerns. I am sending another letter next week.

I’m going to have a meeting with the MHRA very soon to raise our concerns and to see if they can point us in the right direction to receive more expert help and to achieve the goals as above.

The charity has a petition active at this time since January 2011 and I am hoping to present it end of this year although we might feel it necessary to extend the term.

Other

- A future prospect: A POSSIBLE CONFERENCE? Later in the year for us to attend with medical experts and the patients the way forward to help each other.

- Request the need to have experienced sonographers to give the 2D and 3D trans-labial ultrasound for all women! This is not currently offered as the correct imaging test, surgeons are wasting NHS money on MRI, CT Scans and Ultra-scans.

- At a later date: ADVERT FOR MESH INURED MESH PATIENTS

- Important: Independent testing facility for the extracted mesh

I have an extensive database with peer articles collated over the years and many of the articles have been taken down from the internet, there is only a fraction of these articles uploaded to the TVT Mum website as I really want to keep this private until the right person comes along who shows an interest and genuinely wants to help resolve our critical health situation and to change ‘Medical Marketing overtaking Medical Science’

I have had to cope with a tremendous amount of work whilst in ill health and as you can imagine there have been some days I nearly threw in the towel! Besides producing the website I have had to set-up a full charity and achieved it through sheer determination, caring and constantly thinking about the poor ladies needing somewhere for support and help. There have been many times I have gone to bed crying my eyes out but the thought of people having somewhere to turn too kept me going.

The sheer volume of emails, letters and telephone calls has been absolutely unbelievable and difficult for me to cope with on my own, although I do have a few ladies who are kind enough to give the help, support and advice to many women.
Through listening to my heart with dignity and constantly working during difficult times and with sheer determination one day someone will come along and give us the help we all deserve is how I achieved the charity, website and support group today.

Many people who have had the TVT/Mesh surgery will tell you it hasn’t only affected their health but also their quality of life - the truth is harrowing and very disturbing.