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12th January 2012

Strictly Private and Confidential

The Rt Hon David Cameron MP, Prime Minister
10 Downing Street
London
SW1A 2AA

Request: To Present our Petition to 10 Downing Street

Dear Mr Cameron,

About our Petition: Urgent Review on TVT, TVT-Secur,TVTO & TOT Medical Devices and Flat Surgical Mesh used for Prolapse and Hernias

Participants:
Mrs Lorraine Evans Charity Founder
Hayley Martin Charity Secretary
Medical Advisor Obstetrician/Gynaecologist
The Patients
The General Public

We are very concerned the medical devices Trans-Vaginal Tension Free Tape (TVT), Trans-vaginal Tension Free Tape (Mini TVT-Secur), Trans-vaginal Tape Obturator (TVT-O), and Trans-vaginal Tape Obturator (TOT) for Stress urinary incontinence (SUI) and flat surgical mesh related products for Prolapse and Hernias have caused thousands of men and women significant damage to their health and quality of life.

For years there are many people who were not given a fully informed consent or choice of treatments by their consultants. Due to very lax regulatory controls on TVT/Mesh medical devices coming onto the market our research indicates the manufacturers did not do any long term human Randomised Control Trials (RCT's) unfortunately they used us as their guinea pigs and experiments without our consent. The consultants only offered their patients TVT/Meshes as a first choice of treatment for stress urinary incontinence (SUI) even for mild incontinence. We later found out through research and confirmed by a medical expert 'most of the time surgical intervention is totally unnecessary' this is the same with flat surgical mesh for prolapse and hernias. We were not given a fully informed consent and we were not offered any other alternative treatments.

The TVT's also known as TransVaginal Mesh (TVM) medical devices are made of Synthetic Surgical Polypropylene Mesh (also known as Prolene) and the Mesh comes in many different materials ie: monofilament, multifilament, grades, pore sizes, etc plus the meshes are petroleum coated and arrive in many different kit forms. It is surgically implanted by urologists, gynaecologists and

obstetricians using different surgical implantation methods. One surgical procedure for the TVT is to insert the medical device blindly with large needles ripping through the vaginal tissues.

It is a plastic piece of mesh implanted into our bodies and most us did not know the truth on the make-up of these medical devices if we did know none of us would have given consent to have this operation. Since doing extensive research since 2008 there are Peer articles to prove it is **not** inert for the human body as it is a foreign object inside us causing contamination in the female and male genital area of the human body with constant urinary tract infections (UTI) plus many other uncomfortable symptoms.

It is known and fact through research TVT/Meshes can start to cause problems from day 1 right up to 7 years later and in some cases even later in life and when things go wrong the TVT/Mesh medical devices can never be fully removed from the human body due to the mesh embedded too deeply within the tissues and bone. Some people are facing multiple surgeries to get the mesh removed causing extensive tissue, nerve, bone and organ damage and even risk of puncture to the bladder and bowel both for implantation and extraction. We are all disfigured for life, and some are permanently disabled and housebound living in daily pain and suffering. Some people have lost their homes and careers plus destroyed marriages and families causing financial ruin.

There are many other complications too besides mesh erosion/extrusion associated with TVT/Meshes, there are reports of other health issues since having this TVT/Meshes implant put in their bodies especially the rise in autoimmune diseases, festering boils and abscesses the list is endless, unfortunately many people were not told of any mesh complications associated with the TVT/Mesh medical devices by our consultants. There are no peer articles to show symptoms associated with mesh related complications all the people suffering have had to help each other comparing real life stories and proves we are all facing similar and often the same devastating dilemma on our health and quality of life.

I launched the website TVT Messed up Mesh (TVT Mum) in May 2009 at my own expense and time. I have researched TVT medical devices since 2008 and I have campaigned tirelessly to bring awareness on TVT's/Meshes plus I have helped hundreds of women since this time. I have received thousands of emails, letters and numerous telephone calls from women who approach our charity for help, support and for advice. TVT Mum website is the only self-help support group in the UK at this present time. I approached the NHS for funding and was told due to lack of funding it is impossible to provide the support service.

I am a 'TVT Mesh Sufferer' myself and I became disabled the morning after surgery back in 2005 when I suffered a pulmonary embolus and collapsed lung and nearly died (there are recorded deaths from this TVT surgery showing in the BMJ article) I was in and out of hospital for years after this surgery and during this time I have been diagnosed with Myasthenia Gravis and Diabetes. I was relatively healthy before I had this surgery, the only health issue I had was mild stress urinary incontinence (SUI) I should have had a fully informed consent and offered an informed choice of treatments but I was only offered the TVT and was not told of any complications associated with the TVT medical device. I lost my health, home, career and my husband lost his wife plus as a mother to my sons, one of my sons was only 8 year old when my health went down. This surgery robbed me of my life and this goes for many other people suffering at this time. Our medical expert who supports our cause quoted 'most of the time surgical intervention is totally unnecessary'.

Through my persistence and determination working on the TVT Mum website whilst in ill health these past 6 years it has now become a very informative, extensive and popular website for

everyone. Professor Marcus Drake said to me at my last consultation the website is mentioned at Urological conferences.

On 3rd November after years of campaigning to have recognition on our medical condition Professor Marcus Drake confirmed our medical condition as 'Chronic TVT/Mesh Implant Inflammation' We all thank him for his excellent surgical skills trying to remove these TVT's and Meshes, unfortunately there are very few surgeons in the UK who can perform mesh removal/extraction surgery. We need our medical condition recognized for official forms ie: DLA, Insurance etc.

There are very few experienced surgeons in the NHS catchment areas and this is causing distress to many people who are travelling hundreds of miles and some are paying privately for treatment causing financial ruin to many.

The medical world call us 'complex' and most of the time A&E do not know what the TVT's and flat mesh medical devices are and this is also causing more distress to the patients and nurses.

Surgeons and GP's often deny it is the TVT/mesh causing problems and they often refer us onto other consultants to give us help then we find the referred surgeon doesn't know how to correct our health with treatment. On most occasions we have had to search for ourselves to find a surgeon experienced in mesh related complications.

<u>We need action from the Government</u>

We implore you to investigate our critical situation for us as the Medicines and Healthcare products Regulatory Agency (the MHRA) have only issued a very small public health notice showing on their website saying they have launched an investigation, unfortunately this is not having much impact considering we are in all suffering severe health issues and it doesn't show how complex this has become within the Medical World.

Research indicates we need a full investigation on the following items:-

- Reclassification on medical devices
- The Medicines and Healthcare products Regulatory Agency (MHRA)
- Under-reporting from the surgeons and patients for years possibly since the 1950's
- A Public Health Notice to be issued urgently similar to the FDA
- A National TVT/Mesh Register
- The Manufacturers
- The CE directive re-evaluation
- Dedicated multi-disciplinary teams around the UK
- Peer articles
- Informed consent and choice of alternative treatments plus Medical Device information
- Patient Health, Safety, Financial ruin and Quality of Life
- Research and current investigations

Brief to Support Bullet Point Items

1. **Reclassification on Medical Devices**

Quoted by our Medical Expert:
I have looked at all the previous MHRA warnings in obstetrics and gynaecology on the MHRA website and it is clear that this is by far the most important and significant warning that has ever been given. The only other warning that comes even close is the one about the use of endometrial ablation

The thalidomide scandal led to the improved regulation of drugs. Likewise, the vaginal mesh scandal should lead to equivalent controls for Class IIb and Class III Medical Devices. This has been called for in the recent articles in the BMJ and the Dispatches Programme as well as the articles about cardiology devices and vaginal mesh from the European journals.

Vaginal mesh should be a Class III and not a Class IIb Medical Device.

The introduction of thalidomide had a great deal of resemblance to vaginal mesh. There were no long term studies in humans but the drug was clearly beneficial in the treatment of early pregnancy symptoms and had some advantages over the previous use of barbiturates. Similarly vaginal mesh appears to be beneficial in some patients but has serious unacceptable side effects in a substantial number of those treated.

POOR REGULATION OF MEDICAL DEVICES

The problem is that medical devices are not subject to the same scrutiny as drugs. Drugs must go through three Trial Phases and are usually subject to robust RCTs. This does not happen with devices. This is a scandal. Logically, Medical Devices should be subject to a similar process to drugs before receiving a marketing licence.

In addition, most doctors do report drug side effects to the MHRA but surgeons seem to have a mental block about reporting the side effects of new medical devices. The latter may be related to the surgeons ' ego ' as they may worry that such problems reflect their surgical expertise.

BMJ and Channel 4 Dispatches:
Thousands of people face painful and expensive surgery to remove failing medical devices such as metal hip replacements and cardiovascular implants, according to investigations by the BMJ and Channel 4 Dispatches.

Direct Link: http://www.channel4.com/info/press/news/investigations-question-safety-regulation-of-medical-devices

***Food and Drugs Administration (FDA) UPDATE 4th January 2012:**
Based on assessment of Medical Device Reports (adverse event reports) submitted to the FDA, evaluation of the published literature, and the September 2011 Obstetrics-Gynecology Devices Panel meeting, the FDA is considering the recommendation that urogynecologic surgical mesh used for trans-vaginal repair of pelvic organ prolapse (POP) be reclassified from Class II to Class III.

*Direct Link:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProstheticsUroGynSurgicalMesh/default.htm

Cardiologists throughout Europe are calling for a major overhaul and improvement in the regulation of Medical Devices

Direct Link:
http://eurheartj.oxfordjournals.org/content/early/2011/05/13/eurheartj.ehr171.full.pdf

We now have the additional news and concerns with PIP breast implants and with the DuPay ASR Hip Replacement implants.

Regarding the PIP breast implants – Recently in the News Andrew Lansley CBE MP Secretary of State for Health has announced these patients can have their implants removed and they can have their health returned, however, for TVT/Mesh sufferers it's a life sentence of emotional and physical turmoil and most of us are permanently disabled. Please read some of the stories showing on the online petition as attached item 5 we need urgent help please.

2. **The Medicines and Healthcare products Regulatory Agency (MHRA)**
The MHRA should demand that devices are subject to the same rigorous checks as drugs. We have sent out correspondence via email and letters to the MHRA raising our concerns and also through our website. To this date they have done very little to improve our situation.

When we have the report back from the MHRA there appears to be excuses from the manufacturer. In my own case they blamed the faulty TVT medical device on the pulmonary embolis clearly this is nothing to do with the actual medical device that caused me to have mesh erosion through the urethra and I had to face more surgery to remove part of the mesh, I still to this day have constant UTI infections, pain, discharge and other uncomfortable symptoms from the TVT.

Quoted by our Medical Expert:
Surgeons rarely report vaginal tape and mesh complications to the NRLS of the NPSA. Probably barely 1% of serious complications are reported. This could be greatly improved if there was National Register of Mesh Complications with compulsory reporting. We should push for this. National and Trust Registers have been used for other new interventional procedures e.g. fibroid embolisation. The reporting is compulsory and provides comprehensive evidence of relative risks and benefits.

A call for a National TVT/Mesh register as quoted by our Medical Advisor - I have no doubt that any Register should be retrospective and ALL previous patients should be contacted to discover the true extent of the problem.

Our health situation is critical. Please can you ask the MHRA to issue a Public Health Notice urgently similar to the Notices issued by the Food and Drugs Association (FDA)

3. **Under-reporting from the surgeons and patients for years possibly since the 1950's**

There is considerable under-reporting and no-one knows the true extent of the problem. No-one in medical practise can say how many TVT/Mesh medical devices and Flat Mesh for other surgeries has been implanted or extracted due to serious surgical mesh complications.

This is a serious growing health problem and it is putting a strain on our NHS to deal with the mesh complications. There is significant numbers showing on the Medicines and Healthcare Products Regulatory Agency (MHRA) database concerning TVT/Mesh medical devices, the adverse reports show these medical devices are faulty and causing severe lifelong health problems and disfigurement and unfortunately death has occurred.

We always encourage all our support group members to submit their adverse reports into the MHRA however, there is nothing anywhere to show the public they can submit an adverse report, the MHRA have said they have sent out posters to health clinics but there are many people who said they have never seen one.

4. **Public Health Notice**

United Kingdom

Dated: 2nd September 2011

The Medicines and Healthcare products Regulatory Agency have only issued a small public health notice on their website.

Direct Link:

http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice%E2%80%93M%E2%80%93T/Syntheticvaginaltapesforstressincontinence/index.htm

Quoted by our Medical Advisor:

I have looked at the previous MHRA MDA alerts in gynaecology over the last few years. There is no doubt that this is by far the most important alert. It concerns not just in one product in fairly limited use but a whole range of products and procedures which are being commonly performed in large number of women but are causing major problems.

United States of America - The Food and Drugs Administration (FDA)

The Food and Drugs Administration in the USA (FDA) have issued two health warnings one in October 2008 and another in July 2011 they are currently carrying out an investigation. It is known mesh related complications are not rare. Latest FDA notice as below:-

Dated: 4th January 2012:

Based on assessment of Medical Device Reports (adverse event reports) submitted to the FDA, evaluation of the published literature, and the September 2011 Obstetrics-Gynecology Devices Panel meeting, the FDA is considering the recommendation that urogynecologic surgical mesh used for transvaginal repair of pelvic organ prolapse (POP) be reclassified from Class II to Class III.

The FDA continues to assess the safety and effectiveness of urogynecologic surgical mesh devices, through:

- Review and analysis of published literature, Medical Device Reports (adverse event reports) submitted to the agency, and post-approval study reports.
- Epidemiological research on safety and effectiveness of surgical mesh, as a part of our effort to better understand possible adverse events associated with surgical mesh for SUI and POP.
- Collaborations with professional societies and other stakeholders to fully understand the postmarket performance of urogynecologic surgical mesh devices, as well as the occurrence of and signs and symptoms associated with specific adverse events.
- Collecting and reviewing all available information about currently marketed urogynecologic surgical mesh devices.
- Mandating postmarket surveillance studies ("522 studies") by manufacturers of urogynecologic surgical mesh devices. On January 03, 2012, the FDA issued:
- 88 postmarket study orders to 33 manufacturers of urogynecologic surgical mesh for POP; and
- 11 postmarket study orders to seven manufacturers of single-incision mini-slings for SUI.

Direct link please refer to item 1 **Food and Drugs Administration (FDA) UPDATE 4th January 2012 page 4**

Dated: 13th July 2011
FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm

Dated: 20th October 2010
FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm

Comment: Our health situation in the UK is critical plus there are very few experienced surgeons in the NHS to treat mesh related complications.

5. **A National TVT/Mesh Register**

Quoted from our Medical Expert:
I have no doubt that any Register should be retrospective and ALL previous patients should be contacted to discover the true extent of the problem.

ARTICLE - EUROPEAN UROLOGY JOURNAL - SYNTHETIC VAGINAL TAPES - PROPOSALS FOR IMPROVED REGULATION

The article demonstrates that the profession is beginning to recognise the problem. It does call for a National Register. This is a major step forward. The BAUS and the BSUG would not produce such an article unless they had serious concerns.

Direct Link: http://www.europeanurology.com/article/S0302-2838(11)00868-2/fulltext

Advice from our Medical Advisor: Proposals for Improved Regulation and a call for a National TVT/Mesh Register – Please read item 3 attached to this letter.

Worldwide Register's reporting adverse incidents for medical devices
http://www.tvt-messed-up-mesh.org.uk/worldwide-registers-reporting-adverse-incidents-for-medical-devices.html

FRANCE
FRENCH MESH REGISTER - BANDELETTES ENQUETE

AFSSAPS, the French equivalent of the MHRA, have had a national mesh register reporting system since 2005. The 2005 Report noticed the concerns about the complications of vaginal mesh. Please type in Google search engine - Bandelettes posees par voie vaginale and click on translate to view in English.

The NETHERLANDS
It appears the Netherlands are proposing a Mesh Register early 2012

6. **The Manufacturers**

Quoted by our Medical Expert:
There is concerns regarding randomized controlled trials (RCT's) the research was based on tissue effects in animal studies rather than studying symptoms in humans.

Experience over the years had always shown that the insertion of foreign bodies in the uro-genital area has always been accompanied by a high risk of pain, infection, erosion and rejection of the materials. The main problem is that there is enormous commercial pressure from the companies that produce these devices. The evidence base is quite poor.

Misrepresentation - The manufacturers have tried to confuse us all on the word TVT most of us thought TVT is the same product throughout the years when in fact there are numerous different products on the market. We were all told at our consultations it is a piece of tape to hold up the urethra and most of us were on the understanding it was a kind piece of woven tape and not this petroleum based plastic synthetic polypropylene mesh. The products are grossly misrepresented to patients. If we all knew the truth the majority of people would have said NO to this surgery.

Peer articles - There are hundreds of peer articles and some prove mesh erosion/protrusion is **not** a rare occurrence. Patients are suffering severe health problems, TVT/Mesh complications, most surgeons have weekend training to implant TVT's but when there are mesh complications very few can take the implant out, shortage of experienced surgeons, we have been used as human guinea pigs and experiments in their trials without informed consent, no human long term randomized controlled trials (RCT's) and the evidence is clear Mesh is NOT inert for the human body.

One important article to read as below:
Degradation, infection and heat effects on polypropylene mesh for pelvic implantation: what was known and when it was known.

Relevant information has accumulated since the 1950s and was available in the medical literature for many years before FDA clearance of various meshes and mesh kits

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3112322/?tool=pubmed

Please read Item 1 for direct link *** Food and Drugs Administration (FDA) UPDATE 4th January 2012 page 4**

Comments: There is no informed leaflet on the TVT/TVT-O/TOT medical devices for SUI and on flat surgical mesh for prolapse and hernias.

The NHS is strained with increasing numbers of people trying to resolve their health issues from these faulty medical devices. The surgeons are stressed with the influx of people going to them for help.

The TVT/Meshes are faulty and should never be in the human body. It is known and fact the TVT/Mesh can erode from day 1 up to 7 possibly longer years later. The TVT/Mesh shrinks, hardens, breaks off and migrates into the surrounding tissues. I have heard it forms peanut size balls and even a large mass in the pelvic area causing much discomfort and pain.

One medial expert has quoted: As the patient and vaginal tissues are aging vaginal atrophy occurs. We are seeing now patients 5-10 years after mesh insertions with mesh erosions and hardening of the vaginal wall.

7. CE Directive

A **Medical Device (MD)** is defined in Directive (93/42/EEC) as: Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for the proper application, intended by the manufacturer to be used for human beings.

Current CE Directive (93/42/EEC)

'active medical device' means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;

Comment: TVT's and Flat Meshes WORK BY USING THE HUMAN POWER SOURCE!

COUNCIL DIRECTIVE of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)

'active implantable medical device' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

Comment: Evidence based peer articles show TVT/Meshes synthetic material medical devices are **not** inert for the human body. It is a permanent implant and the surgeons can never fully remove the mesh as it is too embedded within the tissues.

8. <u>Dedicated Multi-Disciplinary Teams Around the UK</u>

Quoted by our Medical Expert:
The main recommendations for uro-gynaecology appear to be that uro-gynaecologists should be sub-specialty trained and should work with other sub-specialists on multidisciplinary teams.

This is not the case in many NHS hospitals and almost never the case in private practice where consultants work in isolation. The 'conversion' rates (ratio of surgical intervention to new patients) is far higher in private practice and is rarely monitored.

I have seen that some consultants claim to have success rates of 97% but this is almost certainly untrue as the overall success rates of these procedures is probably only about 70 - 75% and about 10-15% will suffer serious complications such as total failure, worsening incontinence, chronic pain and mesh erosion. Pre-operative counselling must be true and objective and must not be used to persuade women to have an operation with such a high risk of side effects. I firmly believe that the TVT and TVTO operations should be stopped until they are fully evaluated in long term RCTs.

It has been suggested that we write to the RCOG and the RCA and the BSU and the BAUS and the NPSA to discuss the need for each regional teaching hospital to nominate a specialist who can deal with mesh complications. Ideal this should be a team consisting of at least one experienced consultant uro-gynaecologist and one consultant urologist working together at the operation.
Whatever the skill and experience of the surgeon, and even the quality of the pre-operative counselling there remains the problem that complications are difficult to predict in any one patient and that complications can be extremely difficult to manage

Quoted by our Medical Expert:
There is also considerable ' marketing ' from gynaecologists who gain financially in USA ' fee for service ' practice and UK private practice. There is also the ' boys with toys ' phenomenon whereby surgeons enjoy trying new procedures.

Quite frankly, many of the UK private gynaecologist's websites are very misleading e.g. quoting over 95% success rates and 0% complications. Websites are unregulated and such claims of success may not stand up to truly objective and independent scrutiny.

There has been an interesting discussion about infected mesh on the Doctors.net website. One specialist said that it was a standing ' joke ' at his centre that they took out more mesh than they put in as they are increasingly have to deal with mesh problems.

It is likely that about 50% of incontinence operations are not necessary and/or make the patient worse. It is often far better to try conservative non-surgical methods and to leave well alone and help the patient adapt to the distressing problem.

9. **Peer Articles**

Misleading information on SLING OPERATION INFORMATION
The new patient information leaflet from the RCOG please refer the link below:

http://www.rcog.org.uk/files/rcog-corp/Mid-urethralSlingRecoveringWell0710.pdf

Quoted by our Medical Advisor:
It does not really say much about long term side-effects such as mesh erosion, pain, and chronic infection. The occurrence of immediate acute problems, e.g perforation of the bladder, also seems to be underplayed. In that sense, the information is misleading.

It does not mention success rates whish seen to vary from about 60-90% depending on the actual procedure and the individual surgeon. I would however be very suspicious of those surgeons who quote high success rates e.g. over 90% as they almost seem to be ' marketing ' the operation.

http://www.dh.gov.uk/en/FreedomOfInformation/Freedomofinformationpublicationschemefeedback/FOIreleases/DH_116520

The McKinsey Report on Achieving World Class Productivity in the NHS.

Slide 54 deals with the Decommissioning of Procedures with Limited Clinical Benefit.

It includes Female genital prolapse/stress incontinence (surgical) and Female genital proplase/stress incontinence (non-surgical)

This has come about because it is recognised that many do not benefit from such procedures and that there has been large amount of unnecessary and unsuccessful surgery. Surgeons who claim that they have success rates of 90% are, quite frankly, lying or distorting the statistics to attract NHS and private patients. Many surgeon websites are very misleading. Obviously, manufacturers will do their best to sweep this under the carpet as they are trying to sell their products; there does tend to be an unrealistic ' new wonder technique ' marketing strategy.

In the NHS, many of these procedures will be decommissioned with expectation that there is much more careful patient selection and provision of information about the result and an end to the marketing approach.

Having said this, it is very important that any money diverted by productivity savings should be used to set up multi-disciplinary teams at regional centres to deal with complex problems and especially the patients who have been damaged by procedures with limited benefit such as mesh surgery.

NICE GUIDELINE - CONSENT FOR PROCEDURES WHERE BENEFITS AND RISKS ARE UNCERTAIN
The patients, who have suffered serious side-effects, might like to consider whether they were adequately counselled according to the NICE Guidelines. I have found that most were not but were, moreover, given unrealistic expectations of an almost miracle new cure.

BMJ article Commentary: Talking to patients about surgical innovations please refer to item 1 attached

10. **Informed Consent**

The consultants are not giving their patients a fully informed consent plus most were not given an informed choice of alternative treatments. We understand surgical intervention is unnecessary in most of cases. Unfortunately many people are only told the normal risks associated with any type of surgery. There are many complications and risks associated with TVT/Mesh related medical devices, most of the people who have had this surgery wouldn't have gone ahead if they had known the make-up of the medical device and the complications.

Quoted by our Medical Expert:
The FDA produced a list of information that must be given to the patient to obtain valid consent. This is supposed to happen in the UK along the lines of the NICE Guidelines on consent for new procedures where the long term effects are unknown. Unfortunately surgeons rarely do this and many of their websites are overtly enthusiastic about these products. Some quoted figures are probably untrue as surgeons may often give testimonials from satisfied patients but never seem to include comments from patients who have suffered failed procedures or major complications.

In English law, all patients should be told about these risks whatever the success rates and skills of the individual surgeon. Even if the risk is low, the unpleasant and serious nature of the complications is a relevant material matter in assisting the patient on whether to give valid consent to proceed or to decline.

Comment: Most of us were not given an informed leaflet or told the exact details on the medical device pre-operative and post- operative. We had no choice but to find out ourselves by accessing our medical records so we could submit our adverse report into the MHRA.

11. Patient Health, Safety, Financial ruin and Quality of Life

Unfortunately over the past years we have come across inexperienced surgeons who have tried to remove TVT/Mesh from their patients unfortunately the outcome has made their health a lot worse for some people to the extent of full bladder removal, nerve, tissue and organ damage causing pain for the rest of their lives, disfigurement with twisted limbs, wheelchair bound after mesh removal and even death.

There are very few experienced uro/gynaecologist surgeons in mesh related complications in the NHS catchment areas and it is costing patients thousands of pounds to receive a private consultation and treatment plus we are travelling hundreds of miles and costing more money in travel expense.

Many people are permanently disfigured and disabled plus people have loss of homes and careers causing distress within our family lives. Marriages and relationships are ruined with break ups happening at a high rate. Family life is destroyed.

These surgeries are affecting both Men and Women and the implants are still continuing today! Our database has hundreds of stories from people seeking help.

The devastation caused by TVT/Mesh is absolutely dire. None of this was our fault we were on the understanding at our original first consultation this so called revolutionary TVT/Mesh surgery will cure us when in fact the it has left many people with life-long disfigurement with

some facing multiple surgeries to remove the mesh. Most of us are living a life of emotional and physical turmoil on a daily basis. We often say to each other - this is not living a healthy, happy, loving life this is a life sentence surviving and existing to try and live.

12. **Research and Current Investigations**
    I have a very large research database consisting of peer articles and hundreds of patient's stories with thousands of emails corresponding to those who have come forward seeking help, support and advice from myself and our charity plus correspondence from experts who are trying to help us.

    Current ongoing investigations by: TVT Messed up Mesh (TVT Mum), Medical Advisor, the Surgeons, BMJ, MHRA, BAUS, RCOG, Dispatches Channel 4 and Rosenblatt Solicitors plus there are other regulatory bodies who have shown interest in this growing serious health problem.

Patient Safety must come first, unfortunately 'Medical Marketing has overtaken Medical Science'

Period Petition is Active

We started our petition back in January 2011 and have an end date for 31st May 2012 we would like to present our petition to 10 Downing Street soon after. There is an active online petition showing stories from people who are affected by TVT/Mesh surgeries and also we have hardcopy petitions for people to sign. To this date we have 809 signatures received from patients and the general public collected without media attention.

Other Considerations

There is far too much information to put in one letter. I really hope this small brief letter gives you an insight on the enormity and scale of the problem and for you to see how serious and complex our situation is at this present time affecting men and women in the UK today.

Ideally, when we present our petition to 10 Downing Street we would like to have the opportunity for an appointment to visit you along with expert's representation to give a clearer view on the current investigations ongoing at this present time concerning TVTs and flat surgical mesh medical devices.

We were told by our medical advisor Obstetrician/Gynaecologist there are thousands of people affected by this serious growing health problem in the UK. They the Medical World don't know how many implants have been done or how many implants have been excised/extracted plus there is serious under-reporting by the surgeons and patients for years.

Thank you for your consideration and to give us your valuable time to read this letter and enclosed documents. I look forward to hearing from you.

Yours sincerely,

Lorraine Evans
Charity Founder
Website: www.tvt-messed-up-mesh.org.uk (known as TVT Mum)

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Attachments
Item 1 British Medical Journal Commentary: Talking to patients about surgical innovations
Item 2 Medical Advisor Advice
Item 3 Proposals for Improved Regulation and a Call for a National TVT/Mesh Register
Item 4 Online Petition Patient Stories
Item 5 Picture Slides from article How to Handle Innovations Polypropylene is not inert in the Human Body By Donald R Ostergard MD

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