PE1517/M

PE01517: Elaine Holmes and Olive McIlroy on behalf of Scottish Mesh Survivors "Hear Our Voice"

Dear Mr Howlett

We would like to thank all Health Boards who have taken time to comment on our petition and welcome the initial sentiment of support for mesh injured women. We would, however, wish to respond to some of the issues raised by Mr Carey, Chief Executive of NHS Grampian. We would like to take this opportunity to assure Mr Carey that we are not at all 'confused' as he seems to suggest. We understand the fundamental differences between Type 1 polypropylene mesh implanted vaginally for prolapse and Type 1 polypropylene mesh implanted vaginally for incontinence. We are very well aware of the differing procedures and subsequent complications specific to each of them, and while the FDA currently only propose to reclassify mesh for prolapse surgery as high risk, we adhere to our position that the evidence supports re-classification for all permanent transvaginal mesh (TVM) procedures, including incontinence surgery.

Mr Carey's letter also seems to suggest that complications suffered by women following polypropylene transvaginal mesh procedure (TVM) for incontinence or prolapse, may not be caused by the actual mesh implant. This is unfair and seeks to minimise the often life-changing complications of many women who have undergone mesh surgery and we wish to challenge that. Mr Carey failed to acknowledge the specific complications resulting from mesh use, namely, mesh erosion, mesh contraction and vaginal shrinkage. These complications are unique to mesh and do not occur following non-mesh surgical procedures. The instruments used to insert the mesh material into the vagina have caused nerve damage when placed too close to certain nerves. This has resulted in significant chronic pain and led to permanent disability for some women. We understand that any surgery has potential complications but strongly believe that placement of mesh inside the vagina has led to new, common and significant complications. We firmly believe the dangers imposed by TVM procedures and further procedures to repair the damage caused do not in any way support Mr Carey's contention that the benefits of mesh procedures outweigh the risks.

While we accept serious complications can happen with non-mesh surgery, literature shows these to be rare. Burch colposuspension and sacrospinous fixation procedures have been performed regularly in the UK since the 1960's and if either procedure fails, then that is the extent of the situation. None of the extremely serious mesh-specific complications can occur. We are not aware of a single litigation case following such procedures. Only transvaginal mesh which has been used in hospitals for the last 15 years has currently 60,000 law suits in the US and many thousands more in other countries. With over 400 cases lodged in the Court of Session, Scotland is now facing the largest medical negligence case in legal history. These figures clearly speak for themselves.

In addition to the obvious human cost, a huge economic cost of further treatment is currently being placed on the shoulders of the NHS here in Scotland as well as in the UK. The drain on the welfare budgets must also be taken into consideration as more women find the complications and further treatments so debilitating, they are forced to leave the workplace. This not only further imposes strain on care and welfare budgets, it also places a considerable burden on victim's families.

One of the biggest failings has been the lack of proper evidence. It is of great concern to us that prolapse TVM continues to be used in Scotland without the good evidence required to support such a position. We appreciate the need to use grafts to augment prolapse surgery, but the current graft material, polypropylene mesh, and the introduction technique being used by surgeons has led to so many life-changing complications, it is now deemed by many as 'defective'. The obvious lack of data is the main reason for our call for temporary suspension and until the evidence gathered in long-term trials such as PROSPECT is published, we believe surgeons must halt mesh procedures.

Mr Carey's letter erroneously suggests that the large majority of patients who have undergone mesh tape procedures to treat incontinence are 'cured'. This clearly contradicts the evidence from the largest randomised study performed on mesh tapes in Scotland, where after only 3 years the success rate was only 73% (Abdel Fattah et al 2012). This suggests that 1 in 4 procedures have failed. The authors have acknowledged a significant reduction in patient-reported success rate compared with the results at 1 year follow up. Such failure rate is seen after 17 years of the standard retropubic incontinence TVM which suggests that the mesh tape most commonly used in Scotland, Ethicon's TVT-O, fails five times faster than the standard one. Therefore the statement suggesting the vast majority are cured seems to be short-sighted. What is also alarming is that in addition to the relatively high failure rate, 6% of the patients had to undergo further surgery in the first 3 years, and we fully expect longer term follow up will see an increase in such percentages. Given the erosion rate added to the plethora of other complications, we should have said 1 in 4 procedures go wrong rather than 1 in 5 as indicated in our petition - we under-estimated the number of procedures going wrong. A 1% risk of serious complications was quoted, is this intraoperative only or does this include following surgery? If it includes the latter, how many years post-op did this figure relate to? The serious complications listed in the SLWG booklet certainly amount to more than 1%.

Medical literature has shown that mesh complications can and do appear many years later. Indeed, the Cabinet Secretary for Health, Alex Neil, has spoken several times about a constituent who reported complications 12 years after having her initial procedure. Because of the widespread failure of doctors and surgeons to report adverse incidents, record data and the destruction of files by several health boards, we fear the true picture of serious complications caused by mesh procedures may never be fully known or understood.

We were surprised Mr Carey raised the issue of anterior repair as an incontinence procedure and an alternative to incontinence mesh. As we understand, anterior repair is not considered an incontinence procedure in this day and age. We believe Mr Carey's use of this procedure to discredit non-mesh surgery as having a high failure rate is misleading. Colposuspension was the 'gold standard' for decades before the introduction of incontinence TVM. Medical evidence shows that it has the same success rate, while avoiding all possible mesh complications. The complications are different, but the rate is certainly not higher. The National Institute of health and Clinical Excellence (NICE) suggested offering colposuspension as a primary procedure for all patients, and they would not have done so if they were not confident in this procedure. NICE also suggested keyhole colposuspension to be provided by experienced surgeons to shorten hospital stay and recovery time. Therefore, we believe it is both unfair and incorrect of Mr Carey to label colposuspension as having a higher complication rate.

We question whether the Health Boards who cite low or no complication rates for TVM procedures include patients who have been referred to specialist centres for treatment? Have these Health Boards used the current BSUG/BAUS database and have they reported all adverse incidents as per MHRA guidelines?

It is alarming that from their comments on the subject, Fife Health Board is clearly unsure of what an adverse incident is, who would be deemed a health professional and where these incidents should be reported to. They say there is no agreement where mesh device information should be recorded in records. We are deeply concerned patient medical records and theatre diaries containing vital evidence for the independent review may have already been destroyed. It is clear that a revision of guidelines is desperately needed and we believe the independent review will highlight other issues.

The highest risk of mesh erosion reported in medical literature is 25% and not the 5% quoted in Grampian's letter. Excision of exposed mesh is not a minor procedure as Mr Carey suggests, and there are many women who have undergone repeated operations to remove mesh exposure – in vain. We would also challenge his assertion that it is 'very rare' to need mesh removed. Indeed, the SLWG patient information and consent booklet has indicated the risk to be uncommon which means it is 1% - this is not 'very rare'. We agree full removal is not possible in many cases and acknowledge and speak from experience that even after removal there are no guarantees symptoms and pain will be resolved.

While we agree that medical recommendation should be based on high quality research as Mr Carey suggests, this high quality research is currently unavailable. We all know that the best studies designed to give an accurate description of the complication rate of any treatment is a large retrospective analysis of registries. Due to the absence of a national registry and lack of mandatory reporting of complications to designated bodies, current short-term RCTs will provide only weak evidence in this respect. Where there are safety concerns and significant under reporting by the medical profession, we strongly believe the only course of action is to temporarily suspend all TVM procedures until good evidence is available.

We understand NHS Grampian has a clear interest in the need for TVM surgery to continue because it serves the interest of the research centres for mesh trials such as PROSPECT, VUE and SIMS, but the temporary suspension of TVM procedures is necessary to independently evaluate evidence and investigate safety. The severity of suffering in mesh injured women is unacceptable and cannot be minimised or ignored. If the evidence finds that mesh (or at least one device) is a defective or problematic product, then potentially thousands of women will be saved from future harm. If the evidence finds that all mesh procedures are safe, then patient fears will be allayed and anyone considering a mesh procedure in future will at least have the benefit of fully informed consent, thanks to the comprehensive booklet produced by the SLWG. The current mesh suspension and independent review has the potential to benefit all. Everyone with patient safety and wellbeing foremost in their thoughts should agree.

Despite being the UK's enforcement authority for medical devices, the industry funded Medicines and Healthcare Regulatory Agency has systematically failed to warn about the devastating injuries suffered by thousands of women across the UK and abroad. Indeed, despite the fact that one of the most commonly used devices in the UK, the Ethicon TVT-O has been found to be defective in a court of law, the MHRA has failed to issue any warnings or advise health boards to trace patients implanted with defective devices as they would if a car defect was identified. While medical mesh firms in the US have been fined hundreds of

millions of pounds over defective devices and patient negligence, and medical firms have offered out of court settlements to victims totalling almost £1.5billion, the MHRA have failed to issue a single medical device alert. Instead, the MHRA continue to state that despite the fines and court awards, 'benefits still outweigh the risks'.

We wish to take this opportunity to challenge the veracity of the figures used by the MHRA to decline any action. Not only have adverse incidents been significantly under reported to the MHRA by health professionals, but when comparing hospital episode statistics (HES), many surgeons have not reported patients with non-surgical complications and due to variable coding used, we believe that there is a significant under estimation of actual numbers, therefore the data contained in the HES database simply does not give an accurate account.

No accurate figures have been kept for patients treated with devices withdrawn from the marketplace by medical companies due to safety concerns, nor does MHRA data reflect the many hospitals and surgeons who have elected not to use TVM. Furthermore, we ask that the Scottish Parliament acknowledge that the 2012 York Report which the MHRA is basing its stance on failed to show any outcomes beyond 24 months, while it is now universally accepted that mesh complications often take many years to emerge.

We urge the MHRA to support a re-classification of these devices to high risk status. This should be done within the European commission laws. Knowing that evidence available to the MHRA is inadequate, we expected a response from the MHRA regarding the Scottish Independent Review to be supportive and encouraging rather than suggesting such review is disproportionate and doubting the likely benefits, time and expenses. With proposals to re-classify TVM devices to high risk by the FDA in the States, the MHRA is expected to lead the way of a similar action in Europe.
We understand that temporary mesh suspension may create a patient backlog and sympathise fully with those suffering from the distressing and uncomfortable symptoms of SUI or POP – we have all been there ourselves and many of us still are. But let's put this into perspective - safety for the masses must be paramount. There is specialist physiotherapy and other non-surgical treatment options as well as non-mesh biological graft alternatives available. No-one is likely to die or end up in a wheelchair for the rest of their lives from incontinence or prolapse. MSP Chic Brodie commented 'misery for one patient is one too many' and thousands of severely mesh injured women around the world will agree.

We welcome support for the use of a Scottish/National register, the mandatory reporting of adverse incidents to the IRIC/MHRA as per guidelines and the referral to specialist centres for women who have sustained mesh injury.

Finally, we thank those Health Boards supporting the current TVM suspension and the independent review and look forward to further discussions by the Petitions Committee.

Yours sincerely

Elaine Holmes and Olive McIlroy